OPP Idenlifier Registration United States Number **Environmental Protection Agency** Amendment Washington, DC 20460 Other Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification EPA File Symbol 524-LOL Sheryl Reilly Company/Product (Name) PM # None Restricted 92 MON 89034 × TC1507 × MON 88017 × DAS-59122-7 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), Monsanto Company my product is similar or identical in composition and labeling to: 800 N. Lindbergh Blvd. EPA Reg. No. St. Louis, MO 63167 Product Name Check if this is a new address Section - II Final printed labels in response to Amendment - Explain below. Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. Other -- Explain below. Notification - Explain below. Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel. Dec 8-9, 2010 Section - III 1. Material This Product Will Be Packaged In: 2. Type of Container Child-Resistant Packaging Water Soluble Packaging Unit Packaging Metal Yes* Yes Yes Plastic Glass If "Yes" If "Yes" * Certification must No. per No. per Paper Unit Packaging Container Package wgt. Container be submitted Other wgt. (Specify) 5. Location of Label Directions 3. Location of Net Contents Information 4. Size(s) Retall Container On Label Container On Labeling accompanying product 6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) > Telephone No. (ไว้ตุlude Area Name Dr. Russell P. Schneider Senior Director, Regulatory Affairs and Gode) (202) 383-2866 Policy Certification 6. Date Application I certify that the statements I have made on this form and att attachments thereto are true, accurate and complète? ** Received I acknowledge that any knowingly fatse or misleading statement may be punishable by fine or imprisonment or both under applicable law. (Stamped) 2. Signature 3. Title Regulatory Affairs Manager 4. Typed Name 5. Date

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95 EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

March 18, 2011

J. Austin Burns Ph.D.

Tel. (314) 694-6514

⊕ EPA

UNITED STATES ENVIRONMENTAL PROJECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data				
Applicant's/Registrant's Name, Address, and Telephone Number: (3) Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,	14) 694-6514	EPA Registration Number / File Symbol: 524-LOL		
Active Ingredient(s) and/or representative test compound(s): Bacilla Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genet ZM1R245, PHP8999, PV-ZM1R39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-	ic Materials (Vectors PV- for their Production in	Date: March 18, 2011		
General Use Pattem(s) (list all those claimed for this product using 40 0	CFR Part 158:	Product Name: MON 89034 × TCI 507 ×		
Terrestrial field crop	<u> </u>	MON 88017 × DAS-59122-7		
NOTE: If your product is a t00% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption				
t am responding to a Data-Call-in Notice, and have included with should be used for this purpose).	rith this form a list of companie	s sent offers of compensation (the Data Matrix form		
Section I: METHOD OF DATA	SUPPORT (Check of	ne method only)		
I am using the cite-all method of support, and have included we this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the selective m	selective method of support (or cite-all option under ethod), and have included with this form a of data requirements (the Data Matrix form must be		
Section II: GEI	NERAL OFFER TO PA	ΔY		
[Required if using the cite-all method or when using the cite-al	Il option under the selective me	thod to satisfy one or more data requirements)		
I hereby offer and agree to pay compensation, to other person		of this application, to the extent required by FIFRA.		
t certify that this application for registration, this form for reregistration for registration, the form for registration, or the Data-Cal method is indicated in Section 1, this application is supported by all dat an identical or substantially similar product, one or more of the ingredie under the data requirements in effect on the date of approval of this apstmilar composition and uses.	II-In response. In addition, if th a in the Agency's files that (1) ents to this product, and (2) is a	e cite-all option or cite-all option under the setective concern the properties or effects of this product or type of data that would be required to be submitted		
I certify that for each exclusive use study cited in support of this registrathe written permission of the original data submitter to cite that study.	ation or reregistration, that I am	the original data submitter or that t have obtained		
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to comprence pegotiations to determine the amount and terms of compensation, if any, to be patd for the use of the study.				
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(f)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should if their to produce such evidence to the Agency upon request, and understand that the Agency may initiate action to deny, cancel or suspend their registration of my product in conformity with FIFRA.				
t certify that the statements t have made on this form and all attacknowingly false of misleading statement may be puntshable by fin		nder the applicable taw.		
Signature /	Date	Typed or Printed Name and วิกันะ ั๋ วั๋		
J. an	3-18-2011	J. Austin Burns ;,,,;, Regulatory Affairs Manager		

Form Approved OMB No. 2070-0060

⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DA	TA MATRIX		10 10 10 10 10 10 10 10 10 10 10 10 10 1	26- 345
		EPA Reg	j. No./File Symbol: 524-L	OL Page t of I
Address: 0 N. Lindbergh Blvd., St. Louis, MO 631	167			07 × MON 88017
Guideline Study Name	MRID Number	Submitter	Status	Note
Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010		Monsanto Company	OWN	This Application
Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010		Monsanto Company	OWN	Additional Supporting IRM Information
in-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date March 18, 2011	
	Address: O. N. Lindbergh Blvd., St. Louis, MO 631 Sis Cry1A.105, Cry2Ab2, Cry tF, Cry3Bb1, Cry34/35A Production in MON 89034 × TC1507 × MON 88017 × Guideline Study Name Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010 Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010	O N. Lindbergh Blvd., St. Louis, MO 63167 Sis CrylA.105, Cry2Ab2, CrylF, Cry3Bb1, Cry34/35Ab1 Proteins and the Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OE Guideline Study Name MRID Number Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010 Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010	Address: O N. Lindbergh Blvd., St. Louis, MO 63167 is CrylA.105, Cry2Ab2, CrytF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genctic Materials (Vectors PV-ZM Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034 Guideline Study Name Administrative Materials for Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010 Monsanto Company Dow AgroSciences' and Monsanto's Response to Uncertainties Raised by the SmartStax® RIB Scientific Advisory Panel, Dec 8-9, 2010 Monsanto Company	Address: O. N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 × TC150 × DAS-59122-7 is Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZM Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-Ø15Ø7-1 × MON-8903



Monsanto Company

07-CR-192E-E2

Page 4 of 5

Form Approved OMB No. 2070-0060

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 f37), U.S. Environmental Protection Agency, 40f M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX Date: February 14, 2011 EPA Reg. No./File Symbol: 524-LOL Page t of t Applicants/Registrant's Name & Address: Product: MON 89034 × TC1507 × MON 88017 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 × DAS-59122-7 Ingredients: Bacillus thuringiensis Cryl A. 105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7) Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note This OWN Application Monsanto Company Additional Supporting IRM Monsanto Company OWN Information Signature Date Name and Title March 18, 2011 J. Austin Burns, Ph.D. Regulatory Affairs Manager

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



Monsanto Company

07-CR-192E-E2

Page 5 of 5



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

March 1, 2011

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

RUSSELL P. SCHNEIDER MONSANTO COMPANY 1300 I STREET, NW, SUITE 450 EAST WASHINGTON, DC 20005-

PRODUCT NAME: MON 89034 X TC1507 X MON 88017 X DAS-59122-7

COMPANY NAME: MONSANTO COMPANY

OPP IDENTIFICATION NUMBER: EPA FILE SYMBOL: 524-LOL EPA RECEIPT DATE: 02/16/11

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 92, at (703) 308-8269.

Sincerely,

P. L. Magne Front End Processing Staff

Information Services Branch

Information Technology & Resources Management Division

Fee for Service



This package includes the following ○ New Registration ○ Amendment ☑ Studies? ☐ Fee Waiver? ☐ volpay % Reduction:	for Division AD BPPD RD Risk Mgr. 92
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date: This item is NOT subject to	524-LOL 2/16/2011
Action Code: *Requested: Granted: Amount Due: \$ \$289	Parent/Child Decisions:
Inert Cleared for Intended Use Reviewer: Shelf Remarks: * Did not state Category, but indicate this was a protocol review. Changed to NON-PRIA per Shery Reilly 15	Uncleared Inert in Product Date: 2/22/11 Date: 4/22/11 Date: 4/22/11



Re: Fw: RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment required for protocol review (EPA file symbol 524-LOL)

Sheryl Reilly to: Teresa Downs

02/28/2011 04: t9 PM

Teresa,

We did ask for this protocol, so it should not be a PRIA submission.

I apologize for any confusion this has caused.

Sheryl

Sheryl K. Reilly, Ph.D. Chief, Microbial Pesticides Branch Biopesticides and Pollution Prevention Division Office of Pesticide Programs (7511P) U.S. Environmental Protection Agency reilly.sheryl@epa.gov 703-308-8269 (phone) 703-308-7026 (fax) Visit http://www.epa.gov/pesticides

Teresa Downs

Good morning, Sheryl, Please see Russ Schnei... 02/28/2011 06:59:27 AM

From:

Teresa Downs/DC/USEPA/US

To:

Shery! Reilly/DC/USEPA/US@EPA

Cc:

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

Date:

02/28/2011 06:59 AM

Subject:

Fw: RESPONSE REQUIRED BY 3/2/1 t; Proof of PRIA fee payment required for protocol review

(EPA file symbol 524-LOL)

Good morning, Sheryl,

Please see Russ Schneider's email below concerning the protocol that you coded last week. Please let me know If you need to see this action; I have it on my desk.

Teresa Downs

Information Services Branch Office of Pesticide Programs

U.S. Environmental Protection Agency

phone: (703)305-5363 fax: (703)305-7670 www.epa.gov/pesticides

---- Forwarded by Teresa Downs/DC/USEPA/US on 02/28/2011 06:56 AM -----

From:

"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>

To:

Teresa Downs/DC/USEPA/US@EPA

Cc: Date: "JENKINS, DANIEL J [AG/1920)" <daniel.j.jenkins@monsanto.com>

02/24/2011 03:50 PM

Subject:

RE: RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment required for protocol review

(EPA file symbol 524-LOL)

Teresa,

Per my voice mail, the protocol we sent to the Biopesticide and Pollution Prevention Division was not for their review, but a response to their request for a protocol that Monsanto uses to certify manufacturing facilities. There should be no fee or PRIA action assigned to this information as it was requested by BPPD as a FYI.

Ĵ

Thanks, and please let me know of your decision.

Russ

Dr. Russell P. Schneider Senior Director, Regulatory Affairs and Policy Monsanto Company 1300 I St., NW Suite 450 East Washington, DC 20005 202/383-2866

----Original Message----

From: Downs.Teresa@epamail.epa.gov [mailto:Downs.Teresa@epamail.epa.gov]

Sent: Thursday, February 24, 2011 3:13 PM

To: SCHNEIDER, RUSSELL P [AG/1920]

Subject: RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment required for

protocol review (EPA file symbol 524-LOL)

Dear Dr. Schneider:

The Biopesticide Division's PRIA team has identified the above action as subject to action code B902. Please email me a pay.gov receipt or a copy of a check in the amount of \$5,789 as proof of fee payment.

Section 33(B][2(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Renewal Act, provides that the fee is due upon submission of the application. We received this action on 2/16/11. If proof of fee payment is not received by COB on 3/2/11, then we will reject this action for non-payment of the PRIA fee and send you an invoice for \$1,448. The Agency is required to collect a minimum of 25% of the applicable fee even if an application is rejected. If you do not pay the invoice by the date specified therein, then the fees will be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

If you have questions about the assignment of the above action code, please contact Sheryl Reilly at reilly.sheryl@epa.gov or (703)308-8269.

Sincerely,

Teresa Downs
Information Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
phone: (703)305-5363
fax: (703)305-7670
www.epa.gov/pesticides
This e-mail message may contain privileged and/or confidential information,
and is intended to be received only by persons entitled
to receive such information. If you have received this e-mail in error, please
notify the sender immediately. Please delete it and

101 (000)

all attachments from any servers, hard drives or any other media. Other use of this e-mail by you is strictly prohibited.

1

All e-mails and attachments sent and received are subject to monitoring, reading and archival by Monsanto, including its subsidiaries. The recipient of this e-mail is solely responsible for checking for the presence of "Viruses" or other "Malware".

Monsanto, along with its subsidiaries, accepts no liability for any damage caused by any such code transmitted by or accompanying this e-mail or any attachment.

The information contained in this email may be subject to the export control laws and regulations of the United States, potentially including but not limited to the Export Administration Regulations (EAR) and sanctions regulations issued by the U.S. Department of Treasury, Office of Foreign Asset Controls (OFAC). As a recipient of this information you are obligated to comply with all applicable U.S. export laws and regulations.



RESPONSE REQUIRED BY 3/2/11: Proof of PRIA fee payment required for protocol review (EPA file symbol 524-LOL)

Teresa Downs to: SCHNEIDER, RUSSELL P [AG/1920]

02/24/2011 03:12 PM

Dear Dr. Schneider:

The Biopesticide Division's PRIA team has identified the above action as subject to action code B902. Please email me a pay.gov receipt or a copy of a check in the amount of \$5,789 as proof of fee payment.

Section 33(B)(2(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Renewal Act, provides that the fee is due upon submission of the application. We received this action on 2/16/11. If proof of fee payment is not received by COB on 3/2/11, then we will reject this action for non-payment of the PRIA fee and send you an invoice for \$1,448. The Agency is required to collect a minimum of 25% of the applicable fee even if an application is rejected. If you do not pay the invoice by the date specified therein, then the fees will be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

If you have questions about the assignment of the above action code, please contact Sheryl Reilly at reilly.sheryl@epa.gov or (703)308-8269.

Sincerely,

Teresa Downs
Information Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
phone: (703)305-5363
fax: (703)305-7670
www.epa.gov/pesticides

Released

Pending receipt of certification of PRIA fee payment

Date placed on hold: 2/24/11 Date released: 3/1/11
Receipt: S- 890647
File Symbol/Reg. #: 524-LOL
Registrant contact information:
Name: Russ Schneider
Phone #/Email address: russell. p. schneider@ monsanto.com
Notes: No fee pay ment 2/24/11 Sent email

Information Services Branch point of contact: Teresa Downs, S-6922, (703)305-5363

United States **Environmental Protection Agency**

Registration	
Amendment	
Other	

OPP Identifier Number

	Washington, DC	20460	Other	
\\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Application for F	Pesticide - Section I		
I. Company/Product Number EPA File Sv	mbol 524-LOL	2. EPA Product Manager Sheryl Reilly		3. Proposed Classification
Company/Product (Name) MON 89034 × TC1507 × M		PM# 92		None Restricted
5. Name and Address of Applicant (In Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167		6. Expedited Review. In according product is similar or identical in a EPA Reg. No.	composition	and labeling to:
	Sec	tion – II		
Notification – Explain Explanation: Use additional page(o below. onse to Agency tetter dated betow. s) if necessary. (For Section I and Sec	Final printed labets Agency letter dated "Me Too" Applicatio Other – Exptain bet	ow.	
Seed Mix Reluge Floducis (R		tion – III		
Material This Product Will Be Pa		1011 – 111		
Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No If "Yes" No. per Unit Packaging Container wgt.	Yes No It "Yes" No. per Package wgt. Container	Plast Glas Pape Othe Specify)	at tic es er
3. Location of Net Contents Information Label Container	n 4. Size(s) Ref	ail Container 5. Loc	ation of Lab n Label	et Directions accompanying product
6. Manner in Which Label is Affixed to	Product Lithogra Paper g Stencile	lued		
		tion – IV	22 - 22 - 22 - 22 - 22 - 22 - 22 - 22	
1. Contact Point (Complete items dire Name Dr. Russell P. Sc	Title	ral to be contacted, if necessary, to proc virector for Regulatory Affairs & Policy	Telep	hone Nुぴ. จัการิเซนีe Area
l certify lhat the statements (hav t acknowledge that any knowingt both under applicable taw.	y false or misleading statement may	ents thereto are true, accurate and comp be punishable by fine or imprisonment o	o/eiè: *; ; ;	13 2 3 3 3
Signature A. Typed Name	3. Title 5. Dat	Regulatory Affairs Manager		, , , , , , , , , , , , , , , , , , , ,
Please read instructions o	Tel. (314) 694-6514 n reverse before completing form. 1-94) Previous editions are obsoleti	February 14, 2011 Form Approved. OMB No. 2070-000 e. White - EPA File Copy (original)		al Expires 2-28-95 Applicant Copy



483940-00

February 14, 2011

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

MONSANTO COMPANY 800 NORTH LINDBERGH BLVD ST. LDUIS, MISSOURI 63167 http://www.monsanto.com

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

Subject: Additional information regarding the manufacturing process and refuge assurance program for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-

59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

Dear Dr. Reilly:

Thank you and your team for the opportunity to review our proposed manufacturing processes for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on February 3, 2011. As requested by Mike Mendelsohn, accompanying this letter is an additional document describing the Monsanto licensee seed conditioner's qualification for seed mix refuge products. This document, in addition to the submission on January 28, 2011 clarifying Monsanto's manufacturing process and standards, addressing both Monsanto-owned and licensee operated facilities should help clarify Monsanto's Refuge Assurance Program for seed mix refuge products (RIB).

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per EERA Section 10(g).

Page 1 of 2

07-CR-192E-E2

Monsanto Company

Documents accompanying this letter:

	Document Cover letter	Category
	Transmittal document	A
	Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	A
48384001	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	В

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely

J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc:

Mr. Mike Mendelsohn, EPA BPPD

Dr. Aian Reynolds, EPA BPPD

Dr. Russell P. Schneider, Monsanto Company

Page 2 of 2

07-CR-192E-E2

Monsanto Company

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

urance Program, including Licensee cts (RIB)
censee Seed Conditioner's
2-14-2011

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

(202) 383-2866

⊕EPA

UNITED STATES ENVIRONMENTAL PROSECTION AGENCY 401 M Street, S. W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the hecessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460,

Do not send the completed form to this address.		nana ua		
Certification with Respect to Citation of Data				
Applicant's/Registrant's Name, Address, and Telephone Number: (31 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, I	EPA Registration Number / File Symbol: 524-LOL			
Active Ingredient(s) and/or representative test compound(s): Bacillu Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-5	Date: February 14, 2011			
General Use Pattem(s) (list all those claimed for this product using 40 C	FR Part 158:	Product Name: MON 89034 × TC1507 ×		
Terrestrial field crop		MON 88017 × DAS-59122-7		
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption				
I am responding to a Data-Call-in Notice, and have included with should be used for this purpose).	ith this form a list of companie	es sent offers of compensation (the Data Matrix form		
Section I: METHOD OF DATA	SUPPORT (Check	one method only)		
I am using the cite-all method of support, and have included withis form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the selective m	selective method of support (or cite-all option under nethod), and have included with this form a of data requirements (the Data Matrix form must be		
Section II: GEN	IERAL OFFER TO P	AY		
(Required if using the cite-all method or when using the cite-all	option under the selective m	ethod to satisfy one or more dala requirements)		
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.				
I certify that this application for registration, this form for reregis the application for registration, the form for registration, or the Data-Call method is indicated in Section 1, this application is supported by all data an identical or substantially similar product, one or more of the ingredier under the data requirements in effect on the date of approval of this application and uses.	-In response. In addition, if the in the Agency's files that (1) hats in this product; and (2) is a	ne cite-all option or cite-all option under the selective concern the properties or effects of this product or a type of data that would be required to be submitted		
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.				
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.				
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Shauld I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.				
I certify1hat the statements t have made on this form and all attac knowingly false of misleading statement may be punishable by fin				
Signature	Date	Typed or Printed Name and Thie '		
J. an	2-14-2011	J. Austin Burns', '';', Regulatory'Affairs Manager'		
		, 12, 22		

Form Approved OMB No. 2070-0060

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.				
	D/	ATA MATRIX			
Oate: February 14, 2011 Applicant's/Registrant's Name & Monsanto Company, 80	Address: 00 N. Lindbergh Blvd., St. Louis, MO 63	167	Produc	leg. No./File Symbol: 524-L0 bt: MON 89034 × TC150 S-59122-7	
Ingredients: Bacillus thuringier	ssis Cryl A.105, Cry2Ab2, Cryl F, Cry3Bb1, Cry34/35/ Production in MON 89034 × TC1507 × MON 88017	Ab1 Proteins and the			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	own	This Application
	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)				Additional Supporting Manufacturing Information
, M			Monsanto Company	OWN	
					<u> </u>
Signature CM			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date February 14, 2011	t
EPA Form 0570-35 (9-	(\$7) Electronic and Paper versions available. Submit only	y Paper version.		Agency Internal Use	е Сору



Form Approved OMB No. 2070-0060

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.				
	78 5	DATA MATRIX			
Date: February 14, 2011			EPA R	eg. No./File Symbol: 524-	LOL Page 1 of t
Applicant's/Registrant's Name 8		C2167		: MON 89034 × TCI:	507 × MON 88017
	00 N. Lindbergh Blvd., St. Louis, MO			S-59122-7	unao I
PHP17662) Necessary for their DAS-59122-7)	nsis Cryl A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34, r Production in MON 89034 × TC1507 × MON 880	735Ab1 Proteins and the C 117 × DAS-59t22-7 (OEC	CD Unique Identifier: MON-890	MIR245, PHP8999, PV-28 34-3 × DAS-Ø15Ø7-1 × M	MIR39, and ION-88Ø17-3 ×
Guldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Additional Supporting Manufacturing Information
Signature		•	Name and Title	Date	
- 1/2 CA	12		J. Austin Burns, Ph.D. Regulatory Affairs Manage	February 14, 20	11

ERA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



Monsanto Company

07-CR-192E-E2

Page 5 of 5



February 14, 2011

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501 Monsanto Company 800 North Linobergh BLVo St. Louis, Missouri 63167 http://www.monsanto.com

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

Subject: Additional information regarding the manufacturing process and refuge assurance program for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

Dear Dr. Reilly:

Thank you and your team for the opportunity to review our proposed manufacturing processes for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on February 3, 2011. As requested by Mike Mendelsohn, accompanying this letter is an additional document describing the Monsanto licensee seed conditioner's qualification for seed mix refuge products. This document, in addition to the submission on January 28, 2011 clarifying Monsanto's manufacturing process and standards, addressing both Monsanto-owned and licensee operated facilities should help clarify Monsanto's Refuge Assurance Program for seed mix refuge products (RIB).

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	A
Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	В

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc:

Mr. Mike Mendelsohn, EPA BPPD

Dr. Alan Reynolds, EPA BPPD

Dr. Russell P. Schneider, Monsanto Company



ì

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

EPA File Symbol 524-LOL

TRANSMITTAL DATE

February 14, 2011

MONSANTO REFERENCE No.

07-CR-192E-E2

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

1

Administrative Materials for Monsanto Protocol/Refuge Assurance Program, i	including Licensee
Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	

MRID Number				

EPA Requested Information

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

MRID Number			
TATELLE TANKING			

Company Official:

J. Austin Burns, Ph.D.

Date

Regulatory Affairs Manager

(314) 694-6514

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

(202) 383-2866

-



Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

(Genuity® SmartStax®; EPA File Symbol 524-LOL)

h

))

OPP Identifier Registration United States Number **Environmental Protection Agency** Amendment Washington, DC 20460 Other Application for Pesticide - Section I 1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification EPA File Symbol 524-LOL Sheryl Reilly Company/Product (Name) PM# None Restricted MON 89034 × TC1507 × MON 88017 × DAS-59122-7 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), 5. Name and Address of Applicant (Include ZIP Code) Monsanto Company my product is similar or identical in composition and labeling to: 800 N. Lindbergh Blvd. EPA Reg. No. St. Louis, MO 63167 Product Name Check if this is a new address Section - II Final printed labels in response to Amendment - Explain below. Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) If necessary, (For Section I and Section II.) Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB) Section - III 1. Material This Product Will Be Packaged In: 2. Type of Container Water Soluble Packaging Child-Resistant Packaging Unit Packaging Metal Yes* Yes Yes Plastic No No Glass * Certification must If "Yes" No. per II "Yes" No. per Paper Package wgt. be submitted Unit Packaging Container Container Other wat. (Specify) 5. Location of Label Directions 3. Location of Net Contents Information 4. Size(s) Retail Container On Label Label Container On Labeling accompanying product Other Lithograph Manner in Which Label is Affixed to Product Paper glued Stenciled Section - IV 1. Contact Point (Complete ilems directly below for identification of Individual to be contacted, if necessary, to process this application.) Name Telephone No. (Include Area Code) Dr. Russell P. Schneider Sr. Director for Regulatory Affairs & (202) 383-2866 Policy Certification 6. Date Application I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. Received I acknowledge that any knowingly false or misteading statement may be punishable by fine or imprisonment or both under applicable law. (Stamped) 2. Signature 3. Title Regulatory Affairs Manager

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original)

Please read instructions on reverse before completing form.

Tel. (314) 694-6514

Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95 White - EPA File Copy (original) Yellow - Applicant Copy

February 14, 2011

J. Austin Burns Ph.D.

4. Typed Name

))

5. Date

&EPA

UI... ED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for jegistration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the Aecessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460.

burden to Director, OPPE Information Management Division (2137), U. Do not send the completed form to this address.	S. Environmental Pro	ection Agency, 401 M Street, S.W., WashIngton DC, 20460.				
Certification with I	Respect to Cita	tion of Data				
Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		EPA Registration Number / File Symbol: 524-LOL				
Active Ingredient(s) and/or representative test compound(s): Bacilla Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genet ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-	PV- Fobrary 14 2011					
General Use Pattem(s) (list all those claimed for this product using 40	CFR Part 158:	Product Name: MON 89034 × TC1507 ×				
Terrestrial field crop	<u> </u>	MON 88017 × DAS-59122-7				
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption						
I am responding to a Data-Call-in Notice, and have included v should be used for this purpose).	vith this form a list of c	ompanies sent offers of compensation (the Data Matrix form				
Section I: METHOD OF DATA	SUPPORT (C	neck one method only)				
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose). I am using the selective method of support (or cite-all of the selective method), and have included with this form completed list of data requirements (the Data Matrix form used).						
Section II: GENERAL OFFER TO PAY						
(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements						
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by F						
Section III: CERTIFICATION						
I certify that this application for registration, this form for reregistrate application for registration, lhe form for registration, or the Data-Cal method is indicated in Section 1, this application is supported by all dat an identical or substantially similar product, one or more of the ingredie under lhe data requirements in effect on the date of approval of this apsimilar composition and uses.	ll-In response. In add a In the Agency's files ints in this product; an	tion, if the cite-all option or cite-all option under the selective that (t) concern the properties or effects of this product or d (2) is a type of data that would be required to be submitted				
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am Ihe original data submitter or that I have obtain the written permission of the original data submitter to cite that study.						
I certify that for each study cited in support of this registration or resubmitter; (b) I have obtained the permission of the original data subcompensation have expired for the study; (d) the study is in the public have offered (i) to pay compensation to the extent required by sect determine the amount and terms of compensation, if any, to be paid for	mitter to use the stud c literature; (e) I have ions 3(c)(1)(F) and/o	y in support of this application; (c) all periods of eligibility for nolified in writing the company that submitted the study and 3(c)(2)(B) of FIFRA; and (li) to commence negotiations to				
I certify that In all inslances where an offer of compensation is require accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are ava such evidence to the Agency upon request, I understand that the Agenconformity with FIFRA.	llable and will be subr	nitted to the Agency upon requesi. Should I fail to produce				
I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.						
Signature	Date	Typed or Printed Name and Title				
J-an	2-14-20	// J. Austin Burns Regulatory Affairs Manager				

Form Approved OMB No. 2070-0060



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

2096 200 26 27 25 20	D/	ATA MATRIX			
Date: February 14, 2011			EF	PA Reg. No./File Symbol: 524-L0	OL Page I of t
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 × TC150 × DAS-59122-7				7 × MON 88017	
	nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35A r Production in MON 89034 × TC1507 × MON 88017 >				
Guldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Compa	ny OWN	This Application
	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Compa	ny OWN	Additional Supporting Manufacturing Information
Signature J. CM	2		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mar	Date February 14, 2011	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency internal Use Copy

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for Ihis collection of information is estimated to average 0.25 hours per response for registration and special review activities, including lime for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, OC 20460. Do not send the form to this address.

	DATA MATRIX			30000		
Date: February 14, 2011	EPA Reg.	Reg. No./File Symbol: 524-LOL Page 1 of 1				
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7			
Ingredients: Bacillus thuringiensis Cryl A.105, Cry2Ab2, Cryl FPHP 17662) Necessary for their Production in MON 89034 × TO DAS-59122-7)	F, Cry3Bb1, Cry34/35AbI Proteins and the Go	enetic Materials (Vectors PV-ZMIF	R245, PHP8999, PV-ZN			
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Nate		
		Monsanto Company	OWN	This Application		
		Monsanto Company	OWN	Additional Supporting Manufacturing Information		
Signature / CM	ailable Submit only Paper version	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date February 14, 201	1		

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Pages 358 - 365

Access to FIFRA health and safety data is restricted under FIFRA section 10(g)

2-14-2011

Proposed language on Monsanto seed-mix conditioner certification

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 with interspersed in-field refuge can only be used by growers planting seed corn specifically generated by qualified seed conditioners licensed by the registrant (Monsanto).

Monsanto must implement a Blended Seed Refuge Assurance Program designed to ensure SmartStax seed mix refuge products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

- 1. Trait purity check on seed lots prior to blending;
- 2. A Quality Management System (QMS) that will include Standard Operating Procedure(s) for the blending process;
- 3. Calibration of blending equipment; and
- 4. Records and data retention records for seed blend products.
 - Calibration records Monsanto and/or licensees will retain equipment calibration documentation for a specified period of time including the procedure, date of calibration, and the results.
 - Blend proportion records (weight and kernel based) Monsanto and/or licensees will
 retain documentation for a specified period of time on the kernel per pound data of the
 components, the calculations to determine the proportions based on weight, and the actual
 weights of the seeds that are blended together to make up the SmartStax seed mix refuge
 product by seed lot.

Facilities that condition RIB products will be responsible for meeting the product and process requirements provided by Monsanto. Such licensed facilities/conditioner must be qualified by Monsanto prior to producing the 95/5% MON 89034 × TC1507 × MON 88017 × DAS-59122-7/non-Bt corn seed mixture for commercial sale (RIB). In order to qualify, Monsanto will require all facilities, including licensees to implement and maintain a Quality Management System (OMS). Key elements of these processes are to be captured as a licensee qualification Refuge Assurance Program. Under this qualification program, a product facility/conditioner will be required to certify that RIB products it produces under this program meet or exceed the Monsanto-mandated product requirements, including a minimum of 5% non-Bt refuge seed per seed lot. Monsanto will validate the facilities/conditioner (site) qualification through appropriate auditing of the QMS and processes relevant to the Monsanto-mandated product requirements. Conditioners will be audited annually. These facilities must document and retain the required information necessary to demonstrate compliance with product and process requirements, and retain documentation of compliance under their QMS program, and as provided by Monsanto under the process requirements. Records of validation inspections for facilities/conditioner compliance will be kept by Monsanto for a minimum period of three years on a rotating schedule. Licensed RIB facilities/conditioners will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results. Licensed RIB facilities/conditioners will also retain documentation

for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up a RIB product by seed lot. Licensed RIB facilities/conditioners will maintain paper and/or electronic production records for a period of at least three years after the lot is sold.

)

PRODUCT LABEL

The subject of this application is for the combined plant-incorporated protectants (PIPs), Bacillus thuringiensis (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 to allow an IRM interspersed in-field refuge configuration. This refuge configuration is enabled by a seed-mixture containing PIP and non-PIP seed. The proposed label for the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, to support an interspersed in-field refuge is attached.

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn
(Alternate Brand Name Genuity® SmartStax® RIB Complete)‡
(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 ×
MON-88Ø17-3 × DAS-59122-7)

Active Ingredients: Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89034-3
Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in corn event MON 89034 (OECD Unique Identifier: MON-89Ø34-3≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in corn event TC1507 (OECD Unique Identifier: DAS- Ø15Ø7-1) ≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 (OECD Unique Identifier: MON-88Ø17-3≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in corn event DAS-59122-7 (OECD Unique Identifier: DAS-59122-7)≤0.0042%*
Other Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material (vector PV-ZMIR39) necessary for its production in corn event MON 88017 ≤ 0.0052%*
PAT protein (phosphinothricin acetyl transferase) and the genetic material (vectors PHP17662 and PHP8999) necessary for its production in corn events TC1507 and DAS-59122-7≤0.00045%* *Maximum percent (wt/wt) of dry forage
‡ Genuity® SmartStax® RIB Complete seed with this refuge configuration contains 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 mixed with at least 5% non-Bt corn within a single lot of seed.
KEEP OUT OF REACH OF CHILDREN
CATIFICAL
CAUTION
NET CONTENTS

EPA Registration No. 524-XXX EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This product may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 corn, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described in the IRM/Grower Guide for MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 corn or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by an IRM/Grower Guide which includes information on planting, production, and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The following information regarding refuge placement for commercial production must be included in the Grower Guide.

This product includes refuge that is interspersed within the field by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed. The seed mix refuge option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 satisfies the refuge requirements in all regions other than in cotton growing regions where corn earworm is a significant pest as defined below. The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each lot of seed corn.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

Additional refuge requirements in cotton-growing regions where corn earworm is a significant pest

In cotton-growing regions where corn earworm is a significant pest, as defined below, the seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed requires the planting of an additional 20% structured refuge (i.e. 20 acres of non-Bt corn for every 80 acres of 95/5 MON 89034 × TC1507 × MON 88017 × DAS-59122-7/non-Bt corn seed mixture planted).

The 20% refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge and the 95/5% MON 89034 × TC1507 × MON 88017 × DAS-59122-7/non-Bt corn seed mixture should be sown on the same day, or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge, or as a separate block that is within ½ mile of the 95/5 MON 89034 × TC1507 × MON 88017 × DAS-59122-7/non-Bt corn seed mixture field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least 4 consecutive rows wide. The refuge can be protected from lepidopteran

Monsanto Company 07-CR-192E-2 Page 4 of 5

damage by use of non-Bt insecticides if the population of one or more target lepidopteran pests of SmartStax[®] (MON 89034 × TC1507 × MON 88017 × DAS-59122-7) in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: __/_/_



483696-00

January 28, 2011

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501 MONSANTO COMPANY 800 NORTH LINOBERGH BLVO. ST. LOUIS, MISSOURI 63167 http://www.monsanto.com

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and

Pollution Prevention Division (7511P)

Subject: Additional information regarding the manufacturing process for a 5% seed mix refuge

for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®:

EPA File Symbol 524-LOL)

Dear Dr. Reilly:

Thank you for the opportunity to review our independent notes resulting from the Scientific Advisory Panel review of the SmartStax seed mix refuge registration application held on December 8-9, 2010 (January 19, 2011 meeting). During our discussion, the EPA BPPD requested that Monsanto (EPA File Symbol 524-LOL) and Dow AgroSciences (EPA File Symbol 68467-RA) independently submit further information clarifying the proposed manufacturing standards for the proposed 5% seed mix refuge product. Accompanying this letter is a document clarifying Monsanto's manufacturing process and standards, addressing both Monsanto-owned and operated facilities, as well as future licensees for the proposed 5% seed mix refuge product.

We trust that the provided information will clarify Monsanto's capabilities and responsibilities with respect to the seed blending manufacturing/process as it pertains to managing IRM compliance with a 5% seed mix refuge as per EPA File Symbol 524-LOL. Additionally, we are providing this information to support a timely EPA registration decision of the product *minimally* within the PRIA decision date of April 12, 2011.

Recent EPA registrations for seed mix refuge corn products (e.g. EPA Reg. Nos. 29964-6'and 29964-10) contained conditions of registration with respect to manufacturing expectations. It is our expectation that similar language should be applicable for other seed mix refuge corn products such as EPA File Symbol 524-LOL, and is appended below (with modification as appropriate). The only proposed change to this language is regarding the use of the ISO-9006 "brand" of Quality Management Systems (QMS), thereby allowing for other equivalent or superior QMS brands and operations to be implemented as appropriate for business operations.

[language from EPA Reg. No. 29964-6, as modified in bold font]

Refuge Assurance Program for SmartStax Seed Mix Refuge Corn

Monsanto must implement a Blended Seed Refuge Assurance Program designed to ensure SmartStax seed mix refuge products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

- 1. Trait purity check on seed lots prior to blending;
- 2. A Quality Management System (QMS), which will include Standard Operating Procedures for the blending process;
- 3. Calibration of blending equipment; and
- 4. Records and data retention records for seed blend products.
 - Calibration records Monsanto and/or licensees will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
 - Blend proportion records (weight and kernel based) Monsanto and/or Licensees will
 retain documentation for a specified period of time on the kernel per pound data of the
 components, the calculations to determine the proportions based on weight, and the actual
 weights of the seeds that are blended together to make up the SmartStax seed mix
 refuge product by seed lot.

All records must be maintained at the Monsanto and/or Licensee blending facility and must be available for the EPA review upon request.

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document	Category
Cover letter	A
Transmittal document	A
Administrative Materials for Additional Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)	A
Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TCI 507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)	В

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely.

J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc:

Mr. Mike Mendelsohn, EPA BPPD

Dr. Alan Reynolds, EPA BPPD

Dr. Russell P. Schneider, Monsanto Company

Dr. Graham Head, Monsanto Company

Monsanto Company

07-CR-192E-E2

Page 3 of 3



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Information regarding the manufacturing process for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®)

EPA File Symbol 524-LOL

TRANSMITTAL DATE

January 28, 2011

MONSANTO REFERENCE No.

07-CR-192E-E2

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

MRID Number		

EPA Requested Information

Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

Date

48369801 MRID Number

Company Official:

Austin Burns, Ph.D.

Regulatory Affairs Manager

(314) 694-6514

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

(202) 383-2866



Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

Monsanto Company

07-CR-192E-E2

Page 1 of 5

United States Registratio Environmental Protection Agency Washington, DC 20460 Other	Number			
Application for Pesticide – Section I				
	osed Classification			
Company/Product (Name) PM # No. No. 100 No. 10	one Restricted			
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 6. Expedited Review. In accordance with FIFRA S my product is similar or identical in composition and lab EPA Reg. No.				
Check if this is a new address				
Section – II				
Amendment - Explain below. Final printed labels in response to Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. Notification - Explain below. Other - Explain below.				
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)				
Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)				
Section - III 1. Material This Product Will Be Packaged In:				
Child-Resistant Packaging Yes Yes No * Certification must be submifted Unit Packaging Yes Yes No. per Unit Packaging Yes Yes No. per Unit Packaging Container Yes No. per Package wgt. Container Water Soluble Packaging Netal Plastic Glass Paper Ofher	r			
3. Location of Net Contents Intomation 4. Size(s) Retail Container	2225			
6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stencifed Section – IV	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3			
f. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application	22 22 222			
Dr. Russell P. Schneider Sr. Director for Regulatory Affairs & Code)).'Ilinciude Area			
Certification I certify that the statements t have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misteading statement may be punishable by fine or imprisonment or both under applicable law.	6. Date Application , ,Received (Stamped)			
2. Signature 3. Title Regulatory Affairs Manager	,			
4Cryped Name J. Austin Burns Ph.D. Tel. (314) 694-6514 January 28, 201 I Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expire	æ 2-28-95			

Monsanto Company

07-CR-192E-E2

Page 2 of 5

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.					
Certification with Respect to Citation of Data					
Applicant's/Registrant's Name, Address, and Telephone Number: (3)	CANADA MARIAN MA	EPA Registration Number / File Symbol;			
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,		524-LOL			
Active Ingredient(s) and/or representative test compound(s): Bacilla Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genet ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-	ic Materials (Vectors PV- for their Production in	Date: January 28, 2 0 11			
General Use Pattern(s) (list all those claimed for this product using 40	CFR Part 158:	Product Name: MON 89034 × TC1507 ×			
Terrestrial field crop	<u> 2000</u>	MON 88017 × DAS-59122-7			
NDTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption					
I am responding to a Data-Call-in Notice, and have included v should be used for this purpose).	vith this form a list of compani	es sent offers of compensation (the Data Matrix form			
Section I: METHOD OF DATA	SUPPORT (Check	one method only)			
t am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose). I am using the selective method of support (or cite-all option the selective method), and have included with this form a completed list of data requirements (the Data Matrix form nused).					
Section II: GE	NERAL OFFER TO P	AY			
(Required if using the cite-all method or when using the cite-all	Il option under the selective m	ethod to satisfy one or more data requirements)			
t hereby offer and agree to pay compensation, to other person	THE PARTY NAMED IN COLUMN TWO IS NOT THE PARTY N	of this application, to the extent required by FIFRA.			
	: CERTIFICATION	1000			
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an Identicat or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of Identical or similar composition and uses.					
I certify that for each exclusive use study cited in support of this registre the written permission of the original data submitter to cite that study.	ation or reregistration, that t a	n the original data submitter or that I have obtained			
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) t am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my production conformity with FIFRA.					
I certify that the statements I have made on this form and all atta knowingly false of misleading statement may be punishable by fir					
Signature	Date	Typed or Printed Name and Ţiţie, ; ,			
J.an	Jan 28,2011	J. Austin Burns			
Regulatory Affairs Manager					

Monsanto Company

07-CR-192E-E2

Page 3 of 5

Form Approved OMB No. 2070-0060

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

D/	ATA MATRIX		THE PROPERTY OF THE PROPERTY O	
	ALTA INVALIANCE	30 (MASA) 10 (MAS) 30	100 VIII VIII VIII VIII VIII VIII VIII V	4.00
Date: January 28, 2011				
	Designation	Produ	uct: MON 89034 × TC15	07 × MON 88017
			A-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1	···
05, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35/ in MON 89034 × TC1507 × MON 88017	Ab1 Proteins and the (× DAS-59122-7 (OE)	Genetic Materials (Vectors PV- CD Unique Identifier: MON-89	ZMIR245, PHP8999, PV-ZN Ø34-3 × DAS-Ø15Ø7-1 × M	IIR39, and ON-88Ø17-3 ×
Study Name	MRID Number	Submitter	Status	Note
trative Materials for Information ag the Manufacturing Process for a Mix Refuge for MON 89034 × × MON 88017 × DAS-59122-7 SmartStax®; EPA File Symbol		Monsanto Company	OWN	This Application
I: Information Regarding the turing Process for a 5% Seed Mix for MON 89034 × TC1507 × 1017 × DAS-59122-7 (Genuity® ax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	Additional Supporting Manufacturing Information
		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag		
	os, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35/ in MON 89034 × TC1507 × MON 88017 Study Name trative Materials for Information ag the Manufacturing Process for a Mix Refuge for MON 89034 × × MON 88017 × DAS-59122-7 SmartStax [®] ; EPA File Symbol 1: Information Regarding the turing Process for a 5% Seed Mix or MON 89034 × TC1507 × 017 × DAS-59122-7 (Genuity [®] ax [®] ; EPA File Symbol 524-LOL)	Study Name Study Name ARID Number MRID Number Mrize Materials for Information In the Manufacturing Process for a Mix Refuge for MON 89034 × X MON 88017 × DAS-59122-7 SmartStax®; EPA File Symbol I: Information Regarding the Sturing Process for a 5% Seed Mix Sor MON 89034 × TC1507 × O17 × DAS-59122-7 (Genuity® Language Symbol 524-LOL)	dbergh Blvd., St. Louis, MO 63167 05, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89 Study Name MRID Number Submitter trative Materials for Information ag the Manufacturing Process for a Mix Refuge for MON 89034 × × MON 88017 × DAS-59122-7 SmartStax®; EPA File Symbol Dil Information Regarding the turing Process for a 5% Seed Mix for MON 89034 × TC1507 × 017 × DAS-59122-7 (Genuity® ax®; EPA File Symbol 524-LOL) Name and Title J. Austin Burns, Ph.D.	05, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZM in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MO Study Name

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version



Monsanto Company -

07-CR-192E-E2

Page 4 of 5

Form Approved OMB No. 2070-0060

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

	DA	ATA MATRIX			
Date: January 28, 2011 EPA Reg. N					OL Page 1 of t
Applicant's/Registrant's Name &			P	roduct: MON 89034 × TC150	07 × MON 88017
	00 N. Lindbergh Blvd., St. Louis, MO 63		The second secon	DAS-59122-7	
Ingredients: Bacillus thuringier PHP17662) Necessary for their DAS-59122-7)	nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35A Production in MON 89034 × TC1507 × MON 88017	Ab1 Proteins and the C DAS-59122-7 (OEC	Genetic Materials (Vectors F CD Unique Identifier: MON	°V-ZMIR245, PHP8999, PV-ZM -89Ø34-3 × DAS-Ø15Ø7-1 × MC	1R39, and 5N-88Ø17-3 ×
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Compa	ny OWN	This Application
			Monsanto Compa	ny OWN	Additional Supporting Manufacturing Information
Signature //			Name and Title	Date	
y ar	Floritonia and Bancourolone available Subaril ante De		J. Austin Burns, Ph.D. Regulatory Affairs Ma	January 28, 2011	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



Monsanto Company

. 07°CR-192E-E2

Page 5 of 5



Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

j

	s ction Agen 20460	су	A	egistratio mendmer ther	Number		
	Applica	tion for P	esticide -	Section I			
Company/Product Number EPA File Sy	mbol 524-LOL		2. EPA Produc		ly	3. Prop	osed Classification
Company/Product (Name) MON 89034 × TC1507 × N	ON 88017 × DAS-	59122-7	PM#	92		N	one Restricted
5. Name and Address of Applicant (In Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167	ocłude ZIP Code)		6. Expedited my product is s EPA Reg. No Product Nam	imilar or Ident	lcal in comp	osition and lab	
Check if this is a new address				·			
		Sect	<u>ion – II </u>				
Amendment – Explain Resubmission in resp Notification – Explain	onse to Agency letter o	lated		Final printed Agency lette "Me Too" Ap Other Exp	er dated optication.	sponse to	
Exptanation: Use additional page(s) If necessary. (For Section I and Section II.)							
Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL) Section — III							
1. Material This Product Will Be Pa	T T				12 TV	pe of Containe	
Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per Container	Water Soluble F Yes No If "Yes" Package wgt.	No. per Container		Metal Plastic Glass Paper Other	
3. Location of Net Contents Information Label Container	n [4. Size(s) Reta	il Container		On Lai	of Label Direct	
6. Manner (n Which Label is Affixed to	Product	Lithograp Paper glt Stenciled	ued !	Other			
1. Contact Point (Complete liems dire	ctly helow for Idenliffca		on – IV	if pacessary	to process	this application	1 -
Name Dr. Russell P. Sc	55 35 55 55 55 55 55 55 55 55 55 55 55 5	Title	rector for Reg Poli	gulatory Aff		Telephone No Code)) 383-2866
I certify Ihal the statements I hav I acknowledge that any knowingt both under applicable law.	e made on this form a		nts therelo are tru	e, accurate ar			6. Date Application Received (Stamped)
2. Signature and		3. Title	Regulatory	Affairs Ma	anager		
4C-Typed Name J. Austin Burns Ph.D. Please read instructions o	Tel. (314) 694-651		January 2 Form Approved		070-0060.	Approvat Explo	es 2-28-95
EPA Form 8570-1 (Rev. 3	-94) Previous edition	s are obsolete				llow - Applica	

Monsanto Company

07-CR-192E-E2

Page 2 of 5

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Do not send the completed form to this address.					
Certification with F	Respect to Citation o	Data			
Applicant's/Registrant's Name, Address, and Telephone Number: (31 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,	EPA Registration Number / File Symbol: 524-LOL				
Active Ingredient(s) and/or representative test compound(s): Bacillus Cry2Ab2, CrytF, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic ZM1R245, PHP8999, PV-ZMIR39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-	Date: January 28, 2011				
General Use Pattem(s) (list all those claimed for this product using 40 the Terrestrial field crop	CFR Part 158:	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7			
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption					
I am responding to a Data-Cali-in Notice, and have included w should be used for this purpose).	ith this form a list of companie	s sent offers of compensation (the Data Matrix form			
Section I: METHOD OF DATA	SUPPORT (Check o	ne method only)			
I am using the cite-all method of support, and have included we this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the selective m	selective method of support (or cite-all option under ethod), and have included with this form a if data requirements (the Data Matrix form must be			
Section II: GEI	NERAL OFFER TO PA	ΑΥ			
(Required If using the cite-ali method or when using the cite-ali I hereby offer and agree to pay compensation, to other person	realight fill are reasonable fill and Reason respective and	로 스타워싱스(1988 - 선택 20대왕) (1982년) : - 전환 (1984년) : - (1984년) : - (1982년) : - 전환 (1984년) (1984년) (1984년) : - (
		of this application, to the extent required by FIFTON.			
Section III: CERTIFICATION I certify that this application for registration, this form for reregistration, or this Data-Call-in response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section t, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of Identical or similar composition and uses.					
I certify that for each exclusive use study cited in support of this registrathe written permission of the original data submitter to cite that study.	ation or reregistration, that I am	the original data submitter or that I have obtained			
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the siudy and have offered (i) to pay compensation to the extent required by sections 3(c)(t)(F) and/or 3(c)(2)(B) of FIFRA; and (li) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation end evidence of their delivery in accordance with sections 3(c)(t)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fall to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.					
t certify that the statements I have made on this form and all attacknowingly faise of misleading statement may be punishable by fin					
Signature	Date	Typed or Printed Name and Title			
J.an	Jan 28,2011	J. Austin Burns Regulatory Affairs Manager			

Form Approved OMB No. 2070-0060

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

	D,	ATA MATRIX			
Date: January 28, 2011		NAME OF THE PARTY	EPA	Reg. No./File Symbol: 524-L	OL Page t of t
Applicant's/Registrant's Name &				luct: MON 89034 × TC150	
	00 N. Lindbergh Blvd., St. Louis, MO 63			AS-59122-7	
	usis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35 r Production in MON 89034 × TC1507 × MON 88017				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	own_	This Application
	Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	, OWN	Additional Supporting Manufacturing Information
Signature 1 an			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date January 28, 2011	

*TEPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency internal Use Copy

GEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington	1, DC 20460. Do not send the form to this addres					
		DATA MATRIX		52 523 52 500		
Date: January 28, 2011			EPA Reg	EPA Reg. No./File Symbol: 524-LOL Page I of		
Applicant's/Registrant's Name &			Product:	MON 89034 × TC1	507 × MON 88017	
Monsanto Company, 80	00 N. Lindbergh Blvd., St. Louis, M	O 63167	× DAS-	59122-7		
	asis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry Production in MON 89034 × TC1507 × MON					
Guldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
			Monsanto Company	OWN	This Application	
			Monsanto Company	OWN	46000000000000000000000000000000000000	
			Monsanto Company	OWN		
Signature Jan	<i></i>		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date January 28, 201	I	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

1

	s ction Agend 20460	cy 📗	-	stration endment	OPP Identifier Number		
	Applica	tion for P	esticide - S	Section I	<u> </u>		
1. Company/Product Number EPA File Sy:	mbol 524-LOL		2. EPA Produc	50.00		3. Propos	ed Classification
Company/Product (Name) MON 89034 × TC1507 × M		59122-7	PM#	92		Non	e Restricted
5. Name and Address of Applicant (In Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 Check if this is a new address	clude ZIP Code)		my product is s EPA Reg. No	I Review. In accommination of identical in the control of the cont	n compositi	ion and labeli	ng to:
		Sect	ion – II				
Amendment Explain Resubmission in respo	onse to Agency letter d	lated		Final printed labe Agency letter dat "Me Too" Applica Other – Explain I	eđ Llon,	nse to	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)							
		Secti	ion – III				
1. Material This Product Will Be Part Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No	No. per Container	Water Soluble P Yes No If "Yes" Package wgt.	ackaging No. per Conialner	M P G P	of Container delal dastic lass aper lher	
3. Location of Net Contents Informatio	n	4. Size(s) Reta	all Container	5. L	ocation of L On Label	abel Directions	******
6. Manner in Which Label Is Affixed to	Product	Lilhograp Paper gla Stenciled	ued	Other			
			on – IV				
1. Contact Point (Complete items direct Name Dr. Russell P. Scl	200 SA	Title	- 1955 AN	ulatory Affairs	Te	lephone No. de)	(Include Area 383-2866
I certify that the statements I have made on this form and all attachments therefo are true, accurate and complete. I acknowledge that any knowingty false or misleading statement may be punishable by fine or imprisonment or hoth under annicable law			Date Application Received Stamped)				
2. Signature 4. Signature 4. Signature 4. Austin Burns Ph.D.	Ге l. (314) 694-651	3. Title	Regulatory	Affairs Manag	ger		
Please read instructions of EPA Form 8570-1 (Rev. 3	reverse before comp.	lettng form.	Form Approved	I. OMB No. 2070- ile Copy (orlginal		roval Expires v - Applicant	

Monsanto Company

07-CR-192E-E2

Page 2 of 5

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and completing the

necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.					
Certification with Respect to Citation of Data					
	Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				
Active Ingredient(s) and/or representative test compound(s): Bactilis Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genet ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-	Date: January 28, 2 0 11				
General Use Pattern(s) (list all those claimed for this product using 40 Terrestrial field crop	CFR Part 158:	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7			
NOTE: If your product is a 100% repackaging of another purchase need to submit this form. You must submit the Formulator's Exemption					
i am responding to a Data-Call-In Notice, and have Included v should be used for this purpose).	with this form a list of compant	es sent offers of compensation (the Data Mairix form			
Section I: METHOD OF DATA	SUPPORT (Check	one method only)			
i am using the cite-ail method of support, and have included we this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the selective r	selective method of support (or cite-all option under nethod), and have included with this form a of data requirements (the Data Matrix form must be			
Section II: GE	NERAL OFFER TO P	AY			
[Required if using the cite-all method or when using the cite-all	(E)				
i hereby offer and agree to pay compensation, to other person		of this application, to the extent required by FIFRA.			
Section III: CERTIFICATION I certify that this application for registration, this form for reregistration, or this Data-Call-in response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.					
I certify that for each exclusive use study cited in support of this registre the written permission of the original data submitter to cite that study.	ation or reregistration, that I a	m the original data submitter or that I have obtained			
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
i certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.					
i certify that the statements I have made on this form and all attachments to It are true, accurate, and complete, i acknowledge that any knowledge to the punishable by fine or imprisonment of both under the applicable law.					
Signature	Date	Typed or Printed Name and Title			
Jan 28,201 J. Austin Burns Regulatory Affairs Manager					

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

n, DC 20460. Do not send the form to this address.		2000 C	(2) 4786X	ECAN XXXX
D,	ATA MATRIX	8		
Date: January 28, 2011				
k Address:		Product	: MON 89034 × TC15	07 × MON 88017
Guideline Study Name	MRID Number	Submitter	Status	Note
Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	This Application
Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Company	OWN	Additional Supporting Manufacturing Information
		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date January 28, 2011	
	Address: O N. Lindbergh Blvd., St. Louis, MO 63 sis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35/ Production in MON 89034 × TC1507 × MON 88017 Guideline Study Name Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL) Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)	Address: O N. Lindbergh Blvd., St. Louis, MO 63167 sis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OE) Guideline Study Name MRID Number Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL) Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL) SmartStax®; EPA File Symbol 524-LOL)	Address: O N. Lindbergh Blvd., St. Louis, MO 63167 Sis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZN Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89033 Guideline Study Name Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL) Volume 1: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL) Monsanto Company Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	DATA MATRIX EPA Reg. No. /File Symbol: 524-I

Monsanto Company

07-CR-192E-E2

Page 4 of 5

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per

		DATA MATRIX			
Date: January 28, 2011			EPA Reg.	No./File Symbol: 524-LC	L Page lofi
	00 N. Lindbergh Blvd., St. Louis,		× DAS-5		
Ingredients: Bacillus thuringien PHP17662) Necessary for their DAS-59122-7)	sis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Production in MON 89034 × TC1507 × MO	Cry34/35Ab1 Proteins and the Gen N 88017 × DAS-59122-7 (OECD	netic Materials (Vectors PV-ZMII Unique Identifier: MON-89Ø34-	R245, PHP8999, PV-ZMI 3 × DAS-Ø15Ø7-1 × MOI	R39, and N-88Ø17-3 ×
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					i ling
S _A					
			Monsanto Company	OWN	This Application
			Monsanto Company Monsanto Company	OWN	44 (337)

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)

۰					2							
	7	3	,	3								
,			>	,								
ŀ	3		3		3							
ŀ	5	3.2	ő	8								
			3			,	2	3	,	,	3	
						2			3		3	
	3					3					3	
,					3							
	1		-	3	3	4	4	,	3	3	3	
,								0	3		0	
ì	5		3	3	3				•	•		
,	Š	-	3		-	3	3					
ì							0.00	,	•	Ē.	4	
			7			3	7	3	7	3	Г	
ŀ				2								
1		3	,	2	3							
•												
			3	,								
ŀ	>	>	3	3	3							
į.												

1

	Environme Wa	United State ntal Protect shington, DC	ction Agen	су	A	egistration mendmen	Number
	Applica	ation for P	esticide – S	Section I			
1. Company/Product Number EPA File Sy	mbol 524-LOL		2. EPA Produc		ly	3. Propo	osed Classification
Company/Product (Name) MON 89034 × TC1507 × M		-59122-7	PM#	 92		M M	one Restricted
5. Name and Address of Applicant (in Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167	clude ZIP Code)		my product is s EPA Reg. No	imilar or ident	ical in comp	osition and labe	1
Check if this is a new address			Product Nam	e			
		Sect	tion – II				
Amendment – Explain Resubmission in resp Notification – Explain	onse to Agency letter below.			Final printed Agency lette "Me Too" Ap Other – Exp	er dated oplication.	sponse to	
Explanation: Use additional page (Information Regarding the Manu 59122-7 (Genuity® SmartStax®;	facturing Process for	or a 5% Seed : 524-LOL)		MON 8903	4 × TC150	7 × MON 880	017 × DAS-
1. Material This Product Will Be Pa	ckaged in:					46.1	
Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No I/ "Yes" Unit Packaging wgt.	No. per Container	Water Soluble F Yes No I/"Yes" Package wgt.	No. per Container	Z. Ty	pe of Container Metal Plasfic Glass Paper Other	
3. Location o/ Net Conlents Information Label Container	n	4. Size(s) Ret	aii Container		5. Location On La	of Label Direct	,,,,,
6. Manner in Which Label is Affixed to	Product	Lithogra Paper gl Stencile	ued	Other			3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3
1. Contact Point (Complete ilems dire	cliv below for Identific	1/0/07/10/1/07		. if necessary.	lo process	this application	.1
Name Dr. Russell P. Sci		T7tle	irector for Reg Poli	gulatory Af		Telephone No Code)	2 (include Area 383 2866
I certify that the statements I hav I ecknowledge that any knowingt both under applicable law.	a made on lhis form a						Date Application Received (Stamped)
2. Signature and		3. Title	Regulatory	Affairs M	anager		**** *********************************
4C-Fyped Name J. Austin Burns Ph.D. Please reed instructions o	Γel. (314) 694-65		January 2 Form Approved		070-0060	Approval Expire	es 2-28-95

Monsanto Company

07-CR-192E-E2

Page 2 of 5

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

burden to Director, O PPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.							
Certification with F	Respect to Cit	ation of Data					
	Applicant's/Registrant's Name, Address, and Telephone Number: (314) 694-6514 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167						
Active Ingredient(s) and/or representative test compound(s): Bacillu Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Geneti ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-5	rs PV. Innuary 29, 2011						
General Use Pattem(s) (list all those claimed for this product using 40 C	FR Part 158:	Product Name: MON 89034 × TC1507 ×					
Terrestrial field crop		MON 88017 × DAS-59122-7					
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption							
! am responding to a Data-Call-in Notice, and have included w should be used for this purpose).	ith this form a list of	companies sent offers of compensation (the Data Matrix form					
Section I: METHOD OF DATA	SUPPORT (C	Check one method only)					
I am using the cile-all method of support, and have included w this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	using the selective method of support (or cite-all option under selective method), and have included with this form a pleted list of data requirements (the Data Matrix form must be d).						
Section II: GEN	NERAL OFFE	R TO PAY					
[Required If using the cite-all method or when using the cite-all							
I hereby offer and agree to pay compensation, to other person	s, with regard to the CERTIFICAT						
I certify that this application for registration, this form for reregis the application for registration, the form for registration, or the Data-Call method is Indicated in Section 1, this application is supported by all data an identical or substantially similar product, one or more of the Ingredie under the data requirements in effect on the date of approval of this application composition and uses.	tration, or this Data I-In response. In ad a in the Agency's file nts in this product, a	-Call-In response is supported by all data submitted or cited in idition, if the cite-all option or cite-all option under the selective es that (1) concern the properties or effects of this product or and (2) is a type of data that would be required to be submitted					
I certify that for each exclusive use study cited in support of this registra the written permission of the original data submitter to cite that study.	ation or reregistratio	ın, that I am the original data submitler or tรักป หลังe oblained					
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I heve obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitter's the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to compensation is determined the amount and terms of compensation, if any, to be paid for the use of the study.							
I certify that In all Instances where an offer of compensation is require accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are avaitable evidence to the Agency upon request, I understand that the Agency conformity with FIFRA.	lable and will be sul cy may inillate actio	bmitted to the Agency upon request. Shoold I fail to produce on to deny, cancel or suspend the registration of my product in					
I certify that the statements I have made on this form and all attacknowingly false of misleading statement may be punishable by fin	thments to it are to e or imprisonment	rue, accurate, and complete. ! acknowlodge that any t of both under the applicable law.					
Signature	Date	Typed or Printed Name and Title					
J.an	Jan 28,3	J. Austin Burns Regulatory Affairs Manager					

Monsanto Company

07-CR-192E-E2

Page 3 of 5

Form Approved OMB No. 2070-0060

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

100 1 00 1 00 1 00 1 00 00 00 00 00 00 0	D	ATA MATRIX			
Date: January 28, 2011		EP.	A Reg. No./File Symbol: 524-I	OL Page 1 of 1	
	00 N. Lindbergh Blvd., St. Louis, MO 63		×I	duct: MON 89034 × TC15 DAS-59122-7	
Ingredlents: <i>Bacillus thuringier</i> PHP 17662) Necessary for their DAS-59122-7)	sis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35/ Production in MON 89034 × TCt507 × MON 88017	Ab1 Proteins and the C × DAS-59122-7 (OEC	Genetic Materials (Vectors PV CD Unique Identifier: MON-8	/-ZMIR245, PHP8999, PV-ZN 19034-3 × DAS-01507-1 × M	4IR39, and ON-88Ø17-3 ×
Suideline Reference Number	Guideline Study Name	MRIO Number	Submitter	Status	Note
	Administrative Materials for Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TCI507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Compan	y OWN	This Application
	Volume I: Information Regarding the Manufacturing Process for a 5% Seed Mix Refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity® SmartStax®; EPA File Symbol 524-LOL)		Monsanto Compan	y OWN	Additional Supporting Manufacturing Information
Signature /		<u> </u>		Date	
signature of an			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	January 28, 2011	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



Monsanto Company

. 07:CR-192E-E

Page 4 of 5

Form Approved OMB No. 2070-0060

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, OC 20460. Do not send the form to this address.

DATA MATRIX

Date: January 28, 2011 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				EPA Reg. No./File Symbol: 524-LOL Page t of t Product: MON 89034 × TC1507 × MON 88017 × DAS-59122-7			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note		
			Monsanto Company	OWN	This Application		
			Monsanto Company	OWN	Additional Supporting Manufacturing Information		
Signature				Date			
Signature Car	<i></i>	a N	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date January 28, 2011	8		

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.

Public File Copy

Monsanto Company

07-CR-192E-E2

Page 5 of 5



December 18, 2009

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST LDUIS, MISBOURI 63137
http://www.monsanto.com

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture, EPA Reg. No. 524-XXX.

Dear Dr. Reilly:

1

Please find the enclosed application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in field corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStaxTM) allowing an interspersed in-field refuge option that is enabled by a seed-mixture containing PlP and non-PlP seed. This refuge option is distinct from those allowed under the SmartStax EPA registration No's: 524-581 (Monsanto) and 68467-7 (Dow AgroSciences).

Monsanto Company and Dow AgroSciences (Dow) have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax). This combined trait corn product is comprised of six PIPs encoded by four independent events that have each undergone safety assessments by EPA. Each of these four events, as well as the SmartStax combined trait product has a separate Section 3 registration with the EPA. Permanent tolerance exemptions are in place for each of the six PIP and two inert marker proteins present in the combined trait product, SmartStax. EPA completed the safety and environmental assessment by of SmartStax leading to the Section 3 registrations, 524-581 and 68467-7, in July, 2009. Because SmartStax is currently registered to allow various discrete 5% structured refuge options, additional product descriptors for seed corn specific for the interspersed refuge option would be used to ensure there is no confusion between the two

[™] SmartStax is a trademark of Monsanto Technology LLC.

SmartStax product offerings. These additional descriptors would be added prominently to seed corn units and associated labels and literature. Monsanto is committed to ensuring this product clarity, and will present plans for these descriptors to EPA at a later time as they are developed.

1

Currently, the majority of U.S. corn production utilizing PIP-containing corn requires a 20% non-insect protected (referred to as non-PIP or non-Bt) discrete structured refuge for insect-protected Bt corn. The majority of these products produce a single Bt toxin mode of action (insect control). The strategy to use two or more effective doses with differing modes of action (so-called pyramiding) as an effective way to combat resistance development is supported by academics and regulators as the most effective strategy to foster the durability of insect-protected biotech crops. SmartStax produces three Bacillus thuringiensis (Bt) protein toxins each with independent modes of action against lepidopteran corn pests, and two Bt protein toxins with independent modes of insect control against corn rootworms. Each insecticidal mode of action provides an effective dose against these pests. Thus, SmartStax represented a step-change in insect control and insect resistance management (IRM) for corn pests, providing multiple effective modes of action for the control of both above-ground lepidopteran pests and the below-ground corn rootworm (CRW) complex, enabling a significant reduction in the required refuge area (5%) in the U.S. Corn Belt compared with single toxin products (20%).

The IRM conditions of registration for SmartStax under registrations 524-581 and 68467-7 require growers in the U.S. Corn Belt (non-cotton growing areas) to plant 5% of their corn acres with a non-Bt common insect refuge for every 95% of their acres of SmartStax. The non-Bt 'common' refuge supports the production of non-resistant adult insects for both the lepidopteran and corn rootworm pests to mate with the respective surviving insects emerging from SmartStax plants, and thus serves as a refuge for both lepidopteran and corn rootworm pests. This non-Bt refuge corn can be placed as a discrete area, either as infield strips, perimeter rows, adjacent block, or as a separate block within 1/2 mile from the SmartStax field. The specific refuge requirements are defined according to the prevailing pests in a given region, and whether plantings occur in major cotton growing regions.

Extensive laboratory and field studies, and conservative mathematical modeling, showed that even with the 5% structured refuge, the rate of resistance evolution should be at least three times slower for SmartStax than existing single toxin products utilized with a 20% refuge. Given the significant improvements in insect control efficacy and spectrum, reduction in refuge, overall improvements in yields and potential for elimination of soil-applied pesticides, SmartStax corn has the potential to produce sizable pecuniary and non-pecuniary benefits for farmers and the environment. The multiple effective dose strategy is a central component of the durable IRM refuge strategy for SmartStax, using a 5% refuge in any field configuration.

Although the SmartStax registration provided data and modeling information to support deployment of various 5% discrete structured refuge option in the Corn Belt, Monsanto and Dow have investigated alternative refuge designs over many years. This includes an interspersed refuge approach (commonly referred to as a 'seed mix', or 'refuge in a bag'),

Monsanto Company 07-CR-192E-2 Page 2 of 6

in which a fixed amount of non-Bt seed would be included within each bag of SmartStax seed corn to create a interspersed distribution of non-Bt refuge plants among the SmartStax corn plants across a field. Seed mixes of Bt and non-Bt seed have been recognized as a possible insect resistance management (IRM) strategy for Bt crops for almost two decades because of the value of having an IRM strategy implemented by the technology provider rather than growers. This removes the issue of grower compliance with the IRM strategy and ensures that a refuge will be present within every Bt crop field. Benefits of an interspersed refuge via seed mixes from an IRM perspective include:

- Consistent percentage of non-Bt plants in every Bt field
- An interspersed in-field distribution of non-Bt plants will be particularly beneficial for very large fields
- Reduced probability of mating between Bt-resistant adults
- Appropriate choice of refuge hybrid ensured
- Identical management of Bt and refuge plants
- No additional insecticide use on refuge plants
- Higher adoption of pyramided varieties, increasing the durability of all Bt traits

A major hindrance to enabling the development and deployment of an interspersed refuge structure in the past has been the minimum 20% refuge size necessary to ensure durability (time to resistance development) of single dose products. In-field refuges above 5% caused unacceptable total field yield losses in an interspersed in-field refuge structure. With the development of SmartStax corn containing two- and three- effective insecticide modes of action against targeted pests, the substantial increase in durability supported a reduction in the refuge from 20% to 5%. The durability of SmartStax with a 5% refuge for both above-ground and below-ground pests also strongly supports a 5% interspersed infield refuge structure, as delivered by planting a seed mix refuge.

The central need for an interspersed refuge – as with any refuge strategy, is that it supports sufficient populations of susceptible target insects while enabling mixing of these insects with any resistant insects surviving in Bt corn fields. Compared with a block refuge, the novel characteristic of a seed mix is the interspersed nature of Bt and non-Bt plants within in a field. This spatial distribution will enhance the mixing of adult insects coming from Bt and non-Bt plants, ensuring that any resistant insects surviving on Bt plants will encounter susceptible insects coming from non-Bt plants, which will be beneficial for IRM. However, this spatial distribution of plants in a field also could increase the likelihood that larval insects may move between Bt and non-Bt plants because all non-Bt plants will have neighboring Bt plants. Thus, it is important to quantify the impacts of this larval movement on the refuge function within an interspersed refuge from a seed mix.

Specifically, two criteria need to be met to confirm that a 5% seed mix refuge is as effective as current refuge options for SmartStax. First, the seed mix should not lead to a biologically significant increase in sub-lethal exposure of larvae to the Bt toxins that could increase selection for Bt resistance. This could occur either through early instar larvae of the target pests moving from Bt plants to non-Bt plants after sub-lethal exposure, or oy

Monsanto Company 07-CR-192E-2 Page 3 of 6

larvae moving from non-Bt to Bt plants as larger, more Bt-tolerant instars. Assessment of this issue requires examining the susceptibility of larvae of different ages to the proteins in SmartStax. Based on extensive data, the expectation is that the enhanced toxicity conferred by the multiple effective modes of action of SmartStax will make it unlikely that larvae will be able to move and survive in this way, particularly for the highly susceptible lepidopteran target pests. Second, the non-Bt plants in the interspersed field seed mix must support sufficient susceptible pest insects to be an adequate refuge. This can be assessed through direct surveys of pest population density on the non-Bt plants, together with appropriate mathematical modeling.

To this aim, this registration application provides data collected over the past three years assessing the efficacy and value of an interspersed 5% in-field refuge option, via a seed mix containing 5% non-Bt refuge seed + 95% SmartStax seed, as an additional refuge strategy for SmartStax corn in the U.S. Corn Belt. Details of these data and analyses are presented in Volume 2 of this submission. The supporting data and information included in this request include (1) data on larval movement and survival in a 5% interspersed infield refuge for the key lepidopteran (European corn borer (ECB) and southwestern corn borer (SWCB)) and coleopteran target pests (primarily western corn rootworm (WCR) and secondarily northern corn rootworm (NCR)); (2) mathematical modeling to demonstrate the acceptable risk of a interspersed 5% in-field refuge strategy compared to existing refuge strategies; (3) data on the efficacy of a 5% interspersed refuge against the target pests, and the impact of the non-Bt plants in the interspersed refuge on overall yield; (4) criteria are described for ensuring and verifying a consistent seed mix percentage during the manufacturing process; and additionally, (5) information outlining the benefits for growers, the public, and environment that would result from the addition of an interspersed refuge option for SmartStax (Volume 3 of this submission).

Presented in Volume 2, laboratory and field data indicate that a 5% seed mix will provide an effective refuge for SmartStax for ECB, SWCB, and the CRW species. For all of these pests, the non-Bt plants in a 5% seed mix consistently supported large populations of susceptible insects, while the SmartStax plants had few or no survivors. Highly conservative mathematical modeling shows that an interspersed refuge strategy will provide comparable or greater durability than 5% structured refuge in the Corn Belt, depending upon compliance with the structured refuge, and greater durability than single Bt products with a 20% refuge. Furthermore, this approach will provide yields comparable to current structured refuge systems but with greater convenience and reduced insecticide use on the refuge, thereby bringing additional benefits beyond those of SmartStax with 5% discretely structured refuge.

Presented in Volume 3, the benefits to growers, the environment, and to society at large will be realized by the addition of an interspersed 5% in-field refuge option for SmartStax. Under all 5% refuge options (the strip or block refuge strategy supported in SmartStax registrations 524-581 and 68467-7, and the interspersed 5% in-field refuge proposed with this application), SmartStax represents significant value to U.S. farmers. There are unique benefits to a SmartStax 5% interspersed refuge above those provided by discrete strip or block refuges. These include substantial non-pecuniary grower benefits, environmental

Monsanto Company 07-CR-192E-2 Page 4 of 6

benefits, and improved compliance with IRM requirements. Enabling growers to broadly plant SmartStax corn with an interspersed in-field refuge will support:

- Reduction or potential elimination of application of soil-applied insecticides
- Reduce potential for corn rootworm insecticides in ground or surface water
- Reduce farm worker exposure to organophosphate insecticides, accidental insecticide spills, and insecticide carryover effects
- Increase simplicity, flexibility, and time savings associated with planting the refuge
- Guarantee grower compliance with IRM requirements
- Provide incentive to growers to switch to pyramided Bt technology, improving durability of Bt corn technology

This request for a registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax) will allow an in-field refuge structure in which the non-Bt refuge plants are interspersed within the SmartStax field. This type of interspersed in-field refuge is a 'structured refuge', as defined by EPA (Biopesticides Registration Action Document for Bt Plant-Incorporated Protectants, October 15, 2001), and would be implemented by growers planting a defined seed mixture comprised of PIP (SmartStax) seed with a fixed amount of non-Bt (refuge) seed. In addition, this interspersed refuge would only be implemented via planting a seed-mixture manufactured by the technology provider (registrants) and appropriately licensed seed producer affiliates. This non-Bt refuge would be complementary to, but distinct from, the refuge structures currently allowed under SmartStax registrations 524-581 and 68467-7 (in-field strips, rows, or blocks).

Monsanto and Dow are hereby requesting a registration for the plant-incorporated protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration. The interspersed refuge would be implemented via a seed mixture in bags of seed corn consisting of 5% non-Bt corn along with 95% SmartStax corn. Seed mixtures to be planted under this option would only be prepared by seed producers licensed by the registrants to ensure consistency and provide adequate refuge in the field.

The documents accompanying this request are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Monsanto Company 07-CR-192E-2 Page 5 of 6

 Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents in .pdf format is also provided.

It is Monsanto's understanding from communications with the EPA BPPD, that the following fee category and amount is appropriate based on the PRIA II Fee Table, effective October 1, 2008.

• Fee category: B881. New Product; SAP review required

• Fee category amount: \$82,688

Documents accompanying this application for registration

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	1	\ \
N/A	A	Transmittal document	V	N
1	A	Volume 1: Administrative volume (redacted copy)	1	7
1	В	Volume 1: Administrative volume	V	
2	В .	Volume 2: Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	1	
3	В	Volume 3: The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax TM Corn	1	

Should you require any additional information regarding this application please feel free to contact Dr. Russell Schneider at 202-383-2866, or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.

Regulatory Affairs Manager

Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD Russell Schneider, Ph.D., Monsanto



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-XXX

TRANSMITTAL DATE

December 18, 2009

MONSANTO REFERENCE No.

07-CR-192E-2

Monsanto Company 07-CR-192E-2 Page 1 of 2

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1. Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRID Number	

Registration Summary and Data

Volume 2. Five Percent Seed Mix Refuge as an Insect Resistance Management Option for

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

MRID Number 47943701

Characterization of Benefits

Volume 3. The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn

MRID Number 47943702

Company Official:

Austin Burns, Ph.D.

Regulatory Affairs Manager

(314) 694-6514

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

(202) 383-2866



February 14, 2011

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501 Monsanto Company 800 North Lindbergn Blvo St. Louis, Missouri 63167 http://www.monsanto.com

Attn: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch, Biopesticide and Pollution Prevention Division (7511P)

Subject: Additional information regarding the manufacturing process and refuge assurance program for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (Genuity[®] SmartStax[®]; EPA File Symbol 524-LOL)

Dear Dr. Reilly:

Thank you and your team for the opportunity to review our proposed manufacturing processes for a 5% seed mix refuge for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 on February 3, 2011. As requested by Mike Mendelsohn, accompanying this letter is an additional document describing the Monsanto licensee seed conditioner's qualification for seed mix refuge products. This document, in addition to the submission on January 28, 2011 clarifying Monsanto's manufacturing process and standards, addressing both Monsanto-owned and licensee operated facilities should help clarify Monsanto's Refuge Assurance Program for seed mix refuge products (RIB).

The documents accompanying this letter have been classified "A" or "B", as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Documents accompanying this letter:

Document Cover letter	Category
Transmittal document	A
Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	A
Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)	В

If you have any questions regarding this submission, please do not hesitate to contact Dr. Russell P. Schneider at 202-383-2866 or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.

Regulatory Affairs Manager, Monsanto Company

cc:

Mr. Mike Mendelsohn, EPA BPPD

Dr. Alan Reynolds, EPA BPPD

Dr. Russell P. Schneider, Monsanto Company



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

EPA File Symbol 524-LOL

TRANSMITTAL DATE

February 14, 2011

MONSANTO REFERENCE No.

07-CR-192E-E2

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

MRID	Number			

EPA Requested Information

Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

MRID Number		
IATIVITY TAMBIDOR		

Company Official:

J. Austin Burns, Ph.D.

Date

Regulatory Affairs Manager

(314) 694-6514

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

(202) 383-2866



Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)

(Genuity® SmartStax®; EPA File Symbol 524-LOL)

1)

OPP Identifier Registration United States Number **Environmental Protection Agency** Amendment Washington, DC 20460 Other Application for Pesticide - Section I 2. EPA Product Manager I. Company/Product Number 3. Proposed Classification EPA File Symbol 524-LOL Sheryl Reilly Company/Product (Name) PM# X None Restricted MON 89034 × TC1507 × MON 88017 × DAS-59122-7 5. Name and Address of Applicant (Include ZIP Code) 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(I), Monsanto Company my product is similar or identical in composition and labeling to: 800 N. Lindbergh Blvd. EPA Reg. No. St. Louis, MO 63167 Product Name Check If this is a new address Section - II Final printed labels in response to Amendment - Explain below. Agency letter dated Resubmission in response to Agency letter dated "Me Too" Application. Other - Explain below. Notification - Explain below. Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB) Section - III 1. Material This Product Will Be Packaged In: 2. Type of Container Child-Resistant Packaging Unit Packaging Water Soluble Packaging Metal Yes* Yes Yes Plastic No No No Glass * Certification must If "Yes" No. per If "Yes" No. per Paper Unit Packaging Container Package wgt. Container be submitted Other (Specify) 5. Localion of Label Directions 3. Location of Net Contents Information 4. Size(s) Retail Container On Label Lahel Confainer On Labeling accompanying product 6. Manner in Which Label is Affixed to Product Lithograph Olher Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Telephone No. (Include Area Code) Dr. Russell P. Schneider Sr. Director for Regulatory Affairs & (202) 383-2866 Policy Certification 6. Date Application I certify Ihal Ihe slatements I have made on this form and all allachments thereto are true, accurate and complete. Received I acknowledge that any knowlngly false or misleading slatement may be punishable by fine or imprisonment or both under applicable law. (Stamped) 2. Signature 3. Title Regulatory Affairs Manager 4. Typed Name 5. Date J. Austin Burns Ph.D. Tel. (314) 694-6514 February 14, 2011 Form Approved. OMB No. 2070-0060. Approval Expires 2-2B-95 Please read instructions on reverse before completing form.

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

€EPA

NITED STATES ENVIRONMENTA_PROTECTION AGENCY 401 M Street, S. W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for 'registration and 0.25 hours per response for reregistration and special review activilies, including time for reading the instructions and completing the 'hecessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Do not send the completed form to this address.	S. Environmental Protection Ag	gency, 401 M Street, S.W., Washington DG, 20460.	
Certification with F	Respect to Citation o	f Data	
Applicant's/Registrant's Name, Address, and Telephone Number: (31 Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,	MO 63167	EPA Registration Number / File Symbol: 524-LOL	
Active Ingredient(s) and/or representative lest compound(s): Bacilla Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic ZM1R245, PHP8999, PV-ZMIR39, and PHP17662) Necessary MON 89034 × TC1507 × MON 88017 × DAS-	Date: February 14, 2011		
General Use Pattern(s) (list all those claimed for this product using 40 C Terrestrial field crop	CFR Part t58:	Product Name: MON 89034 × TC1507 × MON 88017 × DAS-59122-7	
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption			
I am responding to a Data-Call-in Notice, and have included we should be used for this purpose).	rith this form a list of companie	s sent offers of compensation (the Data Matrix form	
Section I: METHOD OF DATA	SUPPORT (Check of	ne method only)	
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose). I am using the selective method of support (or cite-the selective method), and have included with this to completed list of data requirements (the Data Matrix used).			
Section II: GEI	NERAL OFFER TO PA	AY	
(Required If using the cite-all method or when using the cite-all	73	T	
I hereby offer and agree to pay compensation, to other person	s, with regard to the approval	of this application, to the extent required by FIFRA.	
I certify that this application for registration, this form for reregist the application for registration, the form for registration, or the Data-Cal method is indicated in Section t, this application is supported by all dat an identical or substantially similar product, one or more of the ingredie under the data requirements in effect on the date of approval of this apsimilar composition and uses.	stration, or this Data-Call-In res Il-In response. In addition, if th a in the Agency's files that (1) ents in this product; and (2) is a	e cite-all option or cite-all option under the selective concern the properties or effects of this product or type of data that would be required to be submitted	
I certify that for each exclusive use study cited in support of this registrathe written permission of the original data submitter to cite that study.	ation or reregistration, that I am	n the original data submitter or that I have obtained	
I certify that for each study cited in support of this registration or re submitter; (b) I have obtained the permission of the original data sub- compensation have expired for the study; (d) the study is in the public have offered (I) to pay compensation to the extent required by sect determine the amount and terms of compensation, if any, to be paid for	mitter to use the study in supp c literature; (e) I have notified i ions 3(c)(t)(F) and/or 3(c)(2)(ort of this application; (c) all periods of eligibility for in writing the company that submitted the study and	
I certify that in all instances where an offer of compensation is require accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are ava such evidence to the Agency upon request, I understand that the Agen conformity with FIFRA.	ilable and will be submitted to cy may initiate action to deny,	the Agency upon request. Should I fail to produce cancel or suspend the registration of my product in	
I certify that the statements I have made on this form and all atta- knowingly false of misleading statement may be punishable by fin			
Signature	Date	Typed or Printed Name and Title	
J.an	2-14-2011	J. Austin Burns Regulatory Affairs Manager	
AND THE RESIDENCE OF THE PROPERTY OF THE PROPE			

Form Approved OMB No. 2070-0060

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Oivision (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: February 14, 2011			EPA Reg	No./File Symbol: 524-L	OL Page t of t
Applicant's/Registranl's Name & Monsanto Company, 80	00 N. Lindbergh Blvd., St. Louis, MO 63		× DAS-:		
Ingredients: <i>Bacillus thuringier</i> PHP17662) Necessary for their DAS-59122-7)	usis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35A Production in MON 89034 × TC1507 × MON 88017	Ab1 Proteins and the × DAS-59122-7 (OE)	Genetic Materials (Vectors PV-ZMI CD Unique Identifier: MON-89Ø34	R245, PHP8999, PV-ZN -3 × DAS-Ø15Ø7-1 × M	41R39, and ON-88Ø17-3 ×
Guideline Reference Number	Guideline Sludy Name	MRID Number	Submiller	Status	Note
	Administrative Materials for Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	OWN	This Application
	Monsanto Protocol/Refuge Assurance Program, including Licensee Seed Conditioner's Qualification for Seed Mix Refuge Products (RIB)		Monsanto Company	OWN	Additional Supporting Manufacturing Information
Signature CM		2000 18 2006 18 2000	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date February 14, 201	1

Form Approved OMB No. 2070-0060

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per

		DATA MATRIX		48	
Date: February 14, 2011			ЕРА	Reg. No./File Symbol: 524-L(OL Page 1 of 1
Applicant's/Registrant's Name 8 Monsanto Company, 80	Address: 20 N. Lindbergh Blvd., St. Louis, MC	63167		uct: MON 89034 × TC150 AS-59122-7	7 × MON 88017
	ssis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry3 Production in MON 89034 × TC1507 × MON 88				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
No			Monsanto Company	OWN	1
			Monsanto Company	OWN	Manufacturin Information
Signature / CM			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date February 14, 2011	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

PRIA 2 – 21 Day Content Screen Review Worksheet (EPA/OPP Use Only) 3/23/09

21 Da Expe Divis	ay Screen Start Date: \(\frac{12 - 09}{2 - 22 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Processing Signature: \(\frac{3 \cdot 2 - 09}{2 - 09} \) Its In-Pr	_28-0• Date	7 Fee I	Paid: Y	es _ <u>k</u>	-
BPA I	Reg. Number: 524-LOL EPA Receipt Date: 12-	22-	09			
	Items for Review		Yes	No	N/A	
1	Application Form (EPA Form 8570-1)(link to form) signed & coincluding package type	mplete	26 49 	χ		
2	Confidential Statement of Formula all boxes completed, form s dated (EPA Form 8570-4) (Link to form) a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) (See Connects)	nd no	X			
3	Certification with Respect to Citation of Data (EPA Form 8570 form) completed and signed (N/A if 100% repack))-34) (L	ink to	X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	no			44 50-50	
	If applicable, is there a letter of Authorization for exclusive use or	nlv.	25			
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link completed and signed (N/A if source is unregistered or applicant of technical)	to form				X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal at copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if repack)		nal	X		
5	a) Selective Method (Fee category experts use)	yes	no			•
	b) Cite-All (Fee category experts use)				22	Si Si
	c) Applicant owns all data (Fee category experts use)					2 T
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeli (Electronic labels on CD are encouraged and guidance is available;//www.epa.gov/pesticides/regulating/registering/submissions/index.)	lable)(l	ink to	X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X	
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)		4
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)		~
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C. a) List study (or studies) not included with application		

Comments:

The inert ingredients CP4 EPSPS+ PAT Prote well not clear in OPPIN as to whether it was cleared for use therefore, the page is printed and attacked to the CSE. Please confirm whether the inerts are cleared or not. Norman Spurling Spake to a BPPD team member and was told the inerts on the CSF are not in concert format however, we are not clear on that issue I'm sor that we do not have more answers.

Studies (479437) passed 865 review

mp ,2/3/09

479437

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typo graphical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to

http://www.epa.gov/oppbppd1/biopesticides/contacts bppd.html.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw are application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
 number, providing documentation that the inert has been approved, or
 removing the unapproved inert from the CSF or replacing it with one that is
 approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or
- If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.
- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM CR# 09-322

REQUESTOR NAME: N	05000		Request date: 12/29/09
Tel: 305-5835	ORG.: FIRMO	CUBE:	MAIL CODE: 7502 7
	omplete Item A and the o		TC. no shedes ye
FORMATION REQUIRED:			×
A Check Applicable Calegory Provide PCC and Tolerance E Provide PCC for Non-Food U Provide PCC for Active Ingree Provide PCC for Dye. Determine if Fragrance is Acc Other (Describe):	xemption Status For Foo se inert Ingredient (s). dient (s).	Mation.	
ESTICIDE PRODUCT INFORM	ATION:	Men	189034 × 7E 1507 × MEN880
EPA Reg. No/File Symbol: 5	24-LOL	Product N	arne:
Registrant: Men Sinto		Food-Use	Pesticide: [] Yes [] No
Percent in Formulation (For Frag	rance	/Dyes) PM 72
COPPLEAT INCODMATION.	Cal	also con	
edient No.1 Should these of the Circles	hems Rendurdually	per ite lines	del Zare broken out deffer RMATION REPORTED:
THE CONTRACTOR OF THE PROPERTY	hems lindividually		
Trade Name:	fems Sel lindividually	TOL. S	TATUS:
THE CONTRACTOR OF THE PROPERTY	hems Sel Lindividually		TATUS:
Trade Name: CAS Reg. No.: edient No.2:		OTHE	TATUS:
CAS Reg. No.: edient No.2: Chem. Name: 18 50 11 12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		OTHER	TATUS: RINF.: 006496
Trade Name: CAS Reg. No.: edient No.2: Chem. Name: A Sculles + he. Trade Name:		TOL. S OTHER WASI PCC: TOL. S	TATUS: 006496 TATUS:
CAS Reg. No.: edient No.2: Chem. Name: 18 50 11 12 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		OTHER	TATUS: 006496 TATUS:
Trade Name: CAS Reg. No.: edient No.2: Chem. Name: A Sculles + he. Trade Name:		TOL. S OTHER WASI PCC: TOL. S	TATUS: 006496 TATUS:
Trade Name: CAS Reg. No.: edient No.2: Chem. Name: Regulary that Trade Name: CAS Reg. No.:	ringinasis (ny 3	TOL. S OTHER YABI PCC: TOL. S OTHER	TATUS: 006496 TATUS:
Trade Name: CAS Reg. No.: edient No.2: Chem. Name: A gallas the Trade Name: CAS Reg. No.:	ringinasis (ny 3	TOL. S OTHER YABI PCC: TOL. S OTHER	TATUS: ODGGGG TATUS: RINF.:
Trade Name: CAS Reg. No.: edient No.2: Chem. Name: Regulary that Trade Name: CAS Reg. No.: edient No.3 Chem. Name: Base Mass that	ringinasis (ny 3	TOL. S OTHER YABI PCC: TOL. S OTHER	TATUS: 006496 TATUS: 006490 TATUS:
Trade Name: CAS Reg. No.: edient No.2: Chem. Name: A Scilles + he. Trade Name: CAS Reg. No.: edient No.3 Chem. Name: B Scilles + he. Trade Name:	ringinasis (ny 3	TOL. S OTHER GABI TOL. S OTHER AB4 PCC: TOL. S	TATUS: 006496 TATUS: 006490 TATUS:
Trade Name: CAS Reg. No.: chem. Name: A garding that Trade Name: CAS Reg. No.: chem. Name: B garding that Trade Name: CAS Reg. No.: Chem. Name: B garding that Trade Name: CAS Reg. No.:	ringinasis (ny 3	TOL. S OTHER GABI TOL. S OTHER AB4 PCC: TOL. S	TATUS: 006496 TATUS: 006490 TATUS:
Trade Name: CAS Reg. No.: chem. Name: A scalles + he. Trade Name: CAS Reg. No.: chem. Name: B scalles + he. Trade Name: CAS Reg. No.: chem. Name: B scalles + he. Trade Name: CAS Reg. No.:	ringinasis (ny 3	TOL. S OTHER YABI PCC: TOL. S OTHER ABA PCC: TOL. S OTHER	TATUS: 006496 TATUS: 006490 TATUS:

12 30 09

Hello Norman

Shery Reilly was not in, but I apple inth Clan Reynolds and he advised that these pubstances should be left in OPPIN as is. He was also able to address the questions on the inertal as well. These for your guidance on this.

Landy Fort



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

December 28, 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-425260

EPA File Symbol or Registration Number: 524-LOL

Product Name: MON 89034 X TC1507 X MON 88017 X DAS-59122-7

EPA Receipt Date: 22-Dec-2009 EPA Company Number: 524

Company Name: MONSANTO COMPANY

RUSSELL P. SCHNEIDER MONSANTO COMPANY MONSANTO COMPANY 1300 I STREET, NW, SUITE 450 EAST WASHINGTON, DC 20005-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B881

NEW PRODUCT; SAP REVIEW REQUIRED;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

Front End Processing Staff

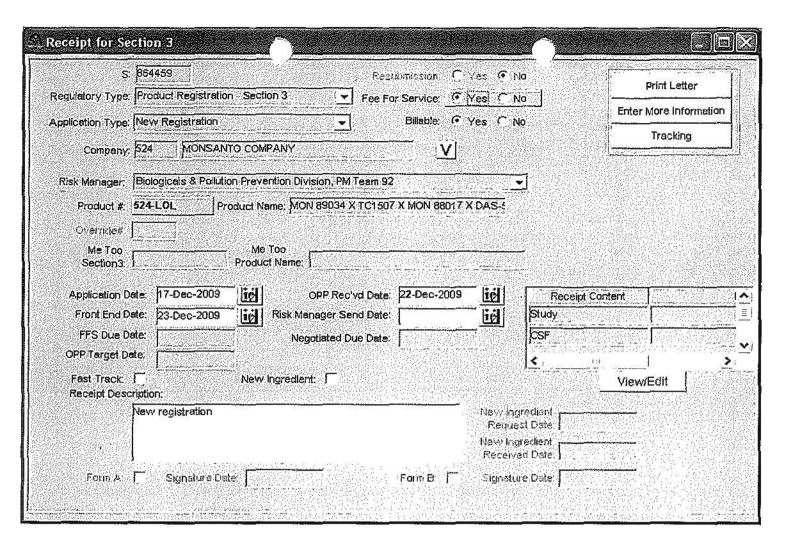
Teresa Dourse

Information Technology & Resources Management Division

Fee for Service

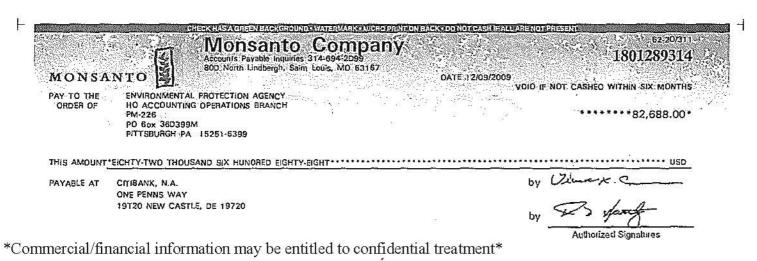
{864459S~

	·
This package includes the following	for Division
New RegistrationAmendment	○ AD ◎ BPPD ○ RD
☑ Studies?☐ Fee Waiver?☐ volpay※ Reduction:	Risk Mgr. 92
Receipt No. S- EPA File Symbol/Reg. No. Pin-Punch Date:	864459 524-LOL 12/22/2009
☐ This item is NOT subject to	FFS action.
Action Code: Requested: 888 Granted: 888 Amount Due: \$82,688	Parent/Child Decisions:
☐ Inert Cleared for Intended Use Reviewer: Alan Reynolds Remarks:	Uncleared Inert in Product Date: 12/23/09



FEE FOR SERVICE

PATENTE 4.210,340, 4227,120, 4.310, 100,5,107,761; 8,340,169



#1801589314#

427

Please read instructions on reverse before completing form.

% EPA	Environmer Was	United States Ital Protect shington, DC 2	ction Agenc	; y [Regist Amen Other	ration dment	OPP Identifier Number
	Applica	tion for P	esticide – S	ection I			
1. Company/Product Number File Sym	abol 524-XXX ∠ 0.	_	2. EPA Produc	t Manager Sheryl Reilly		3. Propos	ed Classification
Company/Product (Name) MON 89034 × TCI 507 ×	MON 88017 × DAS	-59122-7	PM #	92		Non	e Restricted
5. Name and Address of Applicant (I Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 Check if this is a new address	nclude ZIP Code)	0 0	product is simile EPA Reg. No.	Review. In accordance or Identical in co	mposition an	d labeling to:	
		Secti	ion – II		. 4		
Amendment Explai Resubmission in res Notification Explair Exptanation: Use additional page	oonse to Agency letter da i below.			Final printed laborated laborated in Agency letter da "Me Too" Applicated in Control of the Cont	ted ation.	se to	
Application to Register the Plant-Inc Proteins and the Genetic Materials (TC1507 × MON 88017 × DAS-591)	corporated Protectant, Ba Vectors PV-ZMIR245, P 22-7, with an interspersed	cillus thuringie HP8999, PV-Z d in-field refuge	nsis Cryl A.105, MIR39, and PHP	17662) Necessary	for their Pro-	y34Ab1 and duction in M	Cry35AbI [ON 89034 ×
1. Material This Product Will Be P					2. Type of	Containes	
Child-Resistant Packaging Yes* No * Certification must be submitted		No. per Container	Water Soluble Pa Yes No If "Yes" Package wgt.	No. per Contalner	Me	tal stic ess per	
3. Location of Net Contents Information) on T	ـــــــــــــــــــــــــــــــــــــ	I Container	1 5. L	ocation of La	be! Direction	s
Label Container	· ·	71 0125(0) 7 (0)	Various		On Label	accompany	
6. Manner in Which Label Is Affixed to	Product	Lithograph Paper glu Stenciled		Other			
			on – IV	20 29 20 20 20 20 20 20 20 20 20 20 20 20 20			
Conlact Point (Complete items dire Name Russell P. Schne	37 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Title Senior	Director, atory Affairs a		30,500	phone No. (i	Include Area 3-2866
l certify that the statements t hav I acknowledge that any knowingt both under applicable law.	e made on this form and	ertification all attachments	thereto are true, a	accurate and comp	dele.	, , 6	Pate Application Received
2. Signature / CVV	2	3. Title	Regulatory /	Affairs Manage	3 3 2 2 2		. S.
4. Typed Name J. Austin Burns, Ph.D.	Tel. (314) 694-65		December 1	25 2847 25 28		, 2 / 2 / 2 / 2 / 2 / 2 / 2 / 2 / 2 / 2	· ·
EPA Form 8570-1 (Rev. 3-94) Previo			- EPA File Copy	(original) Yellow		ру	,
Monsanto Company	07-CR-1	92E-2		Page 6	of 1/5	', ',≩,;	ນ ົ



December 18, 2009

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501 MONSANTO COMPANY 300 NORTH LINDBERGH BLVD ST LOUIS, MISSOURI 63137 http://www.monsanto.com

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture, EPA Reg. No. 524-XXX.

Dear Dr. Reilly:

Please find the enclosed application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in field corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStaxTM) allowing an interspersed in-field refuge option that is enabled by a seed-mixture containing PIP and non-PIP seed. This refuge option is distinct from those allowed under the SmartStax EPA registration No's: 524-581 (Monsanto) and 68467-7 (Dow AgroSciences).

Monsanto Company and Dow AgroSciences (Dow) have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax). This combined trait corn product is comprised of six PIPs encoded by four independent events that have each undergone safety assessments by EPA. Each of these four events, as well as the SmartStax combined trait product has a separate Section 3 registration with the EPA. Permanent tolerance exemptions are in place for each of the six PIP and two inert marker proteins present in the combined trait product, SmartStax. EPA completed the safety and environmental assessment by of SmartStax leading to the Section 3 registrations, 524-581 and 68467-7, in July, 2009. Because SmartStax is currently registered to allow various discrete 5% structured refuge options, additional product descriptors for seed corn specific for the interspersed refuge option would be used to ensure there is no confusion between the two

[™] SmartStax is a trademark of Monsanto Technology LLC.

SmartStax product offerings. These additional descriptors would be added prominently to seed corn units and associated labels and literature. Monsanto is committed to ensuring this product clarity, and will present plans for these descriptors to EPA at a later time as they are developed.

Currently, the majority of U.S. corn production utilizing PIP-containing corn requires a 20% non-insect protected (referred to as non-PIP or non-Bt) discrete structured refuge for insect-protected Bt corn. The majority of these products produce a single Bt toxin mode of action (insect control). The strategy to use two or more effective doses with differing modes of action (so-called pyramiding) as an effective way to combat resistance development is supported by academics and regulators as the most effective strategy to foster the durability of insect-protected biotech crops. SmartStax produces three Bacillus thuringiensis (Bt) protein toxins each with independent modes of action against lepidopteran corn pests, and two Bt protein toxins with independent modes of insect control against corn rootworms. Each insecticidal mode of action provides an effective dose against these pests. Thus, SmartStax represented a step-change in insect control and insect resistance management (IRM) for corn pests, providing multiple effective modes of action for the control of both above-ground lepidopteran pests and the below-ground corn rootworm (CRW) complex, enabling a significant reduction in the required refuge area (5%) in the U.S. Corn Belt compared with single toxin products (20%).

The IRM conditions of registration for SmartStax under registrations 524-581 and 68467-7 require growers in the U.S. Corn Belt (non-cotton growing areas) to plant 5% of their corn acres with a non-Bt common insect refuge for every 95% of their acres of SmartStax. The non-Bt 'common' refuge supports the production of non-resistant adult insects for both the lepidopteran and corn rootworm pests to mate with the respective surviving insects emerging from SmartStax plants, and thus serves as a refuge for both lepidopteran and corn rootworm pests. This non-Bt refuge corn can be placed as a discrete area, either as infield strips, perimeter rows, adjacent block, or as a separate block within 1/2 mile from the SmartStax field. The specific refuge requirements are defined according to the prevailing pests in a given region, and whether plantings occur in major cotton growing regions.

Extensive laboratory and field studies, and conservative mathematical modeling, showed that even with the 5% structured refuge, the rate of resistance evolution should be at least three times slower for SmartStax than existing single toxin products utilized with a 20% refuge. Given the significant improvements in insect control efficacy and spectrum, reduction in refuge, overall improvements in yields and potential for elimination of scilapplied pesticides, SmartStax corn has the potential to produce sizable pecuniary and non-pecuniary benefits for farmers and the environment. The multiple effective dose strategy is a central component of the durable IRM refuge strategy for SmartStax, using a 5% refuge in any field configuration.

Although the SmartStax registration provided data and modeling information to support deployment of various 5% discrete structured refuge option in the Corn Belt, Monsanto and Dow have investigated alternative refuge designs over many years. This includes an interspersed refuge approach (commonly referred to as a 'seed mix', or 'refuge in a bag'),

Monsanto Company 07-CR-192E-2 Page 2 of 6

in which a fixed amount of non-Bt seed would be included within each bag of SmartStax seed corn to create a interspersed distribution of non-Bt refuge plants among the SmartStax corn plants across a field. Seed mixes of Bt and non-Bt seed have been recognized as a possible insect resistance management (IRM) strategy for Bt crops for almost two decades because of the value of having an IRM strategy implemented by the technology provider rather than growers. This removes the issue of grower compliance with the IRM strategy and ensures that a refuge will be present within every Bt crop field. Benefits of an interspersed refuge via seed mixes from an IRM perspective include:

- Consistent percentage of non-Bt plants in every Bt field
- An interspersed in-field distribution of non-Bt plants will be particularly beneficial for very large fields
- · Reduced probability of mating between Bt-resistant adults
- Appropriate choice of refuge hybrid ensured
- Identical management of Bt and refuge plants
- No additional insecticide use on refuge plants
- Higher adoption of pyramided varieties, increasing the durability of all Bt traits

A major hindrance to enabling the development and deployment of an interspersed refuge structure in the past has been the minimum 20% refuge size necessary to ensure durability (time to resistance development) of single dose products. In-field refuges above 5% caused unacceptable total field yield losses in an interspersed in-field refuge structure. With the development of SmartStax corn containing two- and three- effective insecticide modes of action against targeted pests, the substantial increase in durability supported a reduction in the refuge from 20% to 5%. The durability of SmartStax with a 5% refuge for both above-ground and below-ground pests also strongly supports a 5% interspersed infield refuge structure, as delivered by planting a seed mix refuge.

The central need for an interspersed refuge – as with any refuge strategy, is that it supports sufficient populations of susceptible target insects while enabling mixing of these insects with any resistant insects surviving in Bt corn fields. Compared with a block refuge, the novel characteristic of a seed mix is the interspersed nature of Bt and non-Bt plants within in a field. This spatial distribution will enhance the mixing of adult insects coming from Bt and non-Bt plants, ensuring that any resistant insects surviving on Bt plants will encounter susceptible insects coming from non-Bt plants, which will be beneficial for IRM. However, this spatial distribution of plants in a field also could increase the likelihood that larval insects may move between Bt and non-Bt plants because all non-Bt plants will have neighboring Bt plants. Thus, it is important to quantify the impacts of this larval movement on the refuge function within an interspersed refuge from a seed mix.

Specifically, two criteria need to be met to confirm that a 5% seed mix refuge is as effective as current refuge options for SmartStax. First, the seed mix should not lead to a biologically significant increase in sub-lethal exposure of larvae to the Bt toxins that could increase selection for Bt resistance. This could occur either through early instar larvae of the target pests moving from Bt plants to non-Bt plants after sub-lethal exposure, or oy

Monsanto Company 07-CR-192E-2 Page 3 of 6

larvae moving from non-Bt to Bt plants as larger, more Bt-tolerant instars. Assessment of this issue requires examining the susceptibility of larvae of different ages to the proteins in SmartStax. Based on extensive data, the expectation is that the enhanced toxicity conferred by the multiple effective modes of action of SmartStax will make it unlikely that larvae will be able to move and survive in this way, particularly for the highly susceptible lepidopteran target pests. Second, the non-Bt plants in the interspersed field seed mix must support sufficient susceptible pest insects to be an adequate refuge. This can be assessed through direct surveys of pest population density on the non-Bt plants, together with appropriate mathematical modeling.

To this aim, this registration application provides data collected over the past three years assessing the efficacy and value of an interspersed 5% in-field refuge option, via a seed mix containing 5% non-Bt refuge seed + 95% SmartStax seed, as an additional refuge strategy for SmartStax corn in the U.S. Corn Belt. Details of these data and analyses are presented in Volume 2 of this submission. The supporting data and information included in this request include (I) data on larval movement and survival in a 5% interspersed infield refuge for the key lepidopteran (European corn borer (ECB) and southwestern corn borer (SWCB)) and coleopteran target pests (primarily western corn rootworm (WCR) and secondarily northern corn rootworm (NCR)); (2) mathematical modeling to demonstrate the acceptable risk of a interspersed 5% in-field refuge strategy compared to existing refuge strategies; (3) data on the efficacy of a 5% interspersed refuge against the target pests, and the impact of the non-Bt plants in the interspersed refuge on overall yield; (4) criteria are described for ensuring and verifying a consistent seed mix percentage during the manufacturing process; and additionally, (5) information outlining the benefits for growers, the public, and environment that would result from the addition of an interspersed refuge option for SmartStax (Volume 3 of this submission).

Presented in Volume 2, laboratory and field data indicate that a 5% seed mix will provide an effective refuge for SmartStax for ECB, SWCB, and the CRW species. For all of these pests, the non-Bt plants in a 5% seed mix consistently supported large populations of susceptible insects, while the SmartStax plants had few or no survivors. Highly conservative mathematical modeling shows that an interspersed refuge strategy will provide comparable or greater durability than 5% structured refuge in the Corn Belt, depending upon compliance with the structured refuge, and greater durability than single Bt products with a 20% refuge. Furthermore, this approach will provide yields comparable to current structured refuge systems but with greater convenience and reduced insecticide use on the refuge, thereby bringing additional benefits beyond those of SmartStax with 5% discretely structured refuge.

Presented in Volume 3, the benefits to growers, the environment, and to society at large will be realized by the addition of an interspersed 5% in-field refuge option for SmartStax. Under all 5% refuge options (the strip or block refuge strategy supported in SmartStax registrations 524-581 and 68467-7, and the interspersed 5% in-field refuge proposed with this application), SmartStax represents significant value to U.S. farmers. There are unique benefits to a SmartStax 5% interspersed refuge above those provided by discrete strip or block refuges. These include substantial non-pecuniary grower benefits, environmental

Monsanto Company 07-CR-192E-2 Page 4 of 6

benefits, and improved compliance with IRM requirements. Enabling growers to broadly plant SmartStax corn with an interspersed in-field refuge will support:

- Reduction or potential elimination of application of soil-applied insecticides
- Reduce potential for corn rootworm insecticides in ground or surface water
- Reduce farm worker exposure to organophosphate insecticides, accidental insecticide spills, and insecticide carryover effects
- Increase simplicity, flexibility, and time savings associated with planting the refuge
- Guarantee grower compliance with IRM requirements
- Provide incentive to growers to switch to pyramided Bt technology, improving durability of Bt corn technology

This request for a registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax) will allow an in-field refuge structure in which the non-Bt refuge plants are interspersed within the SmartStax field. This type of interspersed in-field refuge is a 'structured refuge', as defined by EPA (Biopesticides Registration Action Document for Bt Plant-Incorporated Protectants, October 15, 2001), and would be implemented by growers planting a defined seed mixture comprised of PIP (SmartStax) seed with a fixed amount of non-Bt (refuge) seed. In addition, this interspersed refuge would only be implemented via planting a seed-mixture manufactured by the technology provider (registrants) and appropriately licensed seed producer affiliates. This non-Bt refuge would be complementary to, but distinct from, the refuge structures currently allowed under SmartStax registrations 524-581 and 68467-7 (in-field strips, rows, or blocks).

Monsanto and Dow are hereby requesting a registration for the plant-incorporated protectant, *Bacillus thuringiensis* Cryl A.105, Cry2 Ab2, Cryl F, Cry3 Bb1, Cry3 4 Ab1 and Cry3 5 Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration. The interspersed refuge would be implemented via a seed mixture in bags of seed corn consisting of 5% non-Bt corn along with 95% SmartStax corn. Seed mixtures to be planted under this option would only be prepared by seed producers licensed by the registrants to ensure consistency and provide adequate refuge in the field.

The documents accompanying this request are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Monsanto Company 07-CR-192E-2 Page 5 of 6

 Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents in .pdf format is also provided.

It is Monsanto's understanding from communications with the EPA BPPD, that the following fee category and amount is appropriate based on the PRIA II Fee Table, effective October 1, 2008.

Fee category: B881. New Product; SAP review required

Fee category amount: \$82,688

Documents accompanying this application for registration

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A ·	Cover letter	1	\forall
N/A	Α	Transmittal document	V	. √
1	A	Volume 1: Administrative volume (redacted copy)	1	√
1	В	Volume 1: Administrative volume	1	
2 .	В	Volume 2: Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	1	
3	В	Volume 3: The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax [™] Com	1	

Should you require any additional information regarding this application please feel free to contact Dr. Russell Schneider at 202-383-2866, or myself at 314-694-6514.

Sincerely,

1. ans

J. Austin Burns, Ph.D.

Regulatory Affairs Manager

Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD Russell Schneider, Ph.D., Monsanto



1

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-XXX

TRANSMITTAL DATE

December 18, 2009

MONSANTO REFERENCE No.

07-CR-192E-2

Monsanto Company 07-CR-192E-2 Page 1 of 2

435

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1. Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

	MRID Number		
Registratio	on Summary and Data		
	Five Percent Seed Mix Refuge as an Insect Resistance M	fanagement O)ptio
for	MON 89034 × TC1507 × MON 88017 × DAS-59122-7	3 3 2	****
	MRID Number	5 Example 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	3 ,
<u>Character</u> i	zation of Benefits)))))))))))))))))))	, , , ,
Volume 3.	The Benefits of a 5% Interspersed In-field Refuge Optio Corn		ak ^{ŢM}
	MRID Number		, , , , , 1
	MIKID Number		

Company Official:

Mustin Burns, Ph.D.

December 18

Regulatory Affairs Manager

(314) 694-6514

Company Name:

Monsanto Company

Company Contact:

1

Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

07-CR-192E-2

(202) 383-2866

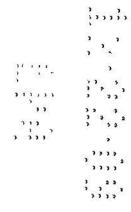


1

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167



REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cryl A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

EPA Registration Number: 524-XXX

TRANSMITTAL DATE

December 18, 2009

MONSANTO REFERENCE No.

07-CR-192E-2

Monsanto Company 07-CR-192E-2 Page 1 of 2

437

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1. Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7. With an Interspersed In-Field Refuge Configuration Using a Seed Mixture

MRID Number	14 M 20 M 2	

Registration Summary and Data

Volume 2. Five Percent Seed Mix Refuge as an Insect Resistance Management Option for

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

MRID	Number		

Characterization of Benefits

Volume 3. The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn

MRID	Number			

Company Official:

Austin Burns, Ph.D.

Date

Regulatory Affairs Manager

(314) 694-6514

Company Name:

Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Senior Director, Regulatory Affairs and Policy

(202) 383-2866

Monsanto Company

07-CR-192E-2



December 18, 2009

1

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

1

Attn: Dr. Sheryl Reilly, Team Leader 92

MORSANIO COMPARY

800 NORTH LINDRERGE BLVO

ST LOUIS, MISSOURI 6313T

http://www.monganio.com

Subject: Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration using a seed mixture, EPA Reg. No. 524-XXX.

Dear Dr. Reilly:

Please find the enclosed application for the registration of the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in field corn (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStaxTM) allowing an interspersed in-field refuge option that is enabled by a seed-mixture containing PIP and non-PIP seed. This refuge option is distinct from those allowed under the SmartStax EPA registration No's: 524-581 (Monsanto) and 68467-7 (Dow AgroSciences).

Monsanto Company and Dow AgroSciences (Dow) have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax). This combined trait corn product is comprised of six PIPs encoded by four independent events that have each undergone safety assessments by EPA. Each of these four events, as well as the SmartStax combined trait product has a separate Section 3 registration with the EPA. Permanent tolerance exemptions are in place for each of the six PIP and two inert marker proteins present in the combined trait product, SmartStax. EPA completed the safety and environmental assessment by of SmartStax leading to the Section 3 registrations, 524-581 and 68467-7, in July, 2009. Because SmartStax is currently registered to allow various discrete 5% structured refuge options, additional product descriptors for seed corn specific for the interspersed refuge option would be used to ensure there is no confusion between the two

SmartStax is a trademark of Monsanto Technology LLC.

SmartStax product offerings. These additional descriptors would be added prominently to seed corn units and associated labels and literature. Monsanto is committed to ensuring this product clarity, and will present plans for these descriptors to EPA at a later time as they are developed.

)

1

Currently, the majority of U.S. corn production utilizing PIP-containing corn requires a 20% non-insect protected (referred to as non-PIP or non-Bt) discrete structured refuge for insect-protected Bt corn. The majority of these products produce a single Bt toxin mode of action (insect control). The strategy to use two or more effective doses with differing modes of action (so-called pyramiding) as an effective way to combat resistance development is supported by academics and regulators as the most effective strategy to foster the durability of insect-protected biotech crops. SmartStax produces three Bacillus thuringiensis (Bt) protein toxins each with independent modes of action against lepidopteran corn pests, and two Bt protein toxins with independent modes of insect control against corn rootworms. Each insecticidal mode of action provides an effective dose against these pests. Thus, SmartStax represented a step-change in insect control and insect resistance management (IRM) for corn pests, providing multiple effective modes of action for the control of both above-ground lepidopteran pests and the below-ground corn rootworm (CRW) complex, enabling a significant reduction in the required refuge area (5%) in the U.S. Corn Belt compared with single toxin products (20%).

The IRM conditions of registration for SmartStax under registrations 524-581 and 68467-7 require growers in the U.S. Corn Belt (non-cotton growing areas) to plant 5% of their corn acres with a non-Bt common insect refuge for every 95% of their acres of SmartStax. The non-Bt 'common' refuge supports the production of non-resistant adult insects for both the lepidopteran and corn rootworm pests to mate with the respective surviving insects emerging from SmartStax plants, and thus serves as a refuge for both lepidopteran and corn rootworm pests. This non-Bt refuge corn can be placed as a discrete area, either as infield strips, perimeter rows, adjacent block, or as a separate block within 1/2 mile from the SmartStax field. The specific refuge requirements are defined according to the prevailing pests in a given region, and whether plantings occur in major cotton growing regions.

Extensive laboratory and field studies, and conservative mathematical modeling, showed that even with the 5% structured refuge, the rate of resistance evolution should be at least three times slower for SmartStax than existing single toxin products utilized with a 20% refuge. Given the significant improvements in insect control efficacy and spectrum, reduction in refuge, overall improvements in yields and potential for elimination of soil-applied pesticides, SmartStax corn has the potential to produce sizable pecuniary and non-pecuniary benefits for farmers and the environment. The multiple effective dose strategy is a central component of the durable IRM refuge strategy for SmartStax, using a 5% refuge in any field configuration.

Although the SmartStax registration provided data and modeling information to support deployment of various 5% discrete structured refuge option in the Corn Belt, Monsanto and Dow have investigated alternative refuge designs over many years. This includes an interspersed refuge approach (commonly referred to as a 'seed mix', or 'refuge in a bag'),

Monsanto Company 07-CR-192E-2 Page 2 of 6

in which a fixed amount of non-Bt seed would be included within each bag of SmartStax seed corn to create a interspersed distribution of non-Bt refuge plants among the SmartStax corn plants across a field. Seed mixes of Bt and non-Bt seed have been recognized as a possible insect resistance management (IRM) strategy for Bt crops for almost two decades because of the value of having an IRM strategy implemented by the technology provider rather than growers. This removes the issue of grower compliance with the IRM strategy and ensures that a refuge will be present within every Bt crop field. Benefits of an interspersed refuge via seed mixes from an IRM perspective include:

- · Consistent percentage of non-Bt plants in every Bt field
- An interspersed in-field distribution of non-Bt plants will be particularly beneficial for very large fields
- Reduced probability of mating between Bt-resistant adults
- · Appropriate choice of refuge hybrid ensured

)

- Identical management of Bt and refuge plants
- No additional insecticide use on refuge plants
- Higher adoption of pyramided varieties, increasing the durability of all Bt traits

A major hindrance to enabling the development and deployment of an interspersed refuge structure in the past has been the minimum 20% refuge size necessary to ensure durability (time to resistance development) of single dose products. In-field refuges above 5% caused unacceptable total field yield losses in an interspersed in-field refuge structure. With the development of SmartStax corn containing two- and three- effective insecticide modes of action against targeted pests, the substantial increase in durability supported a reduction in the refuge from 20% to 5%. The durability of SmartStax with a 5% refuge for both above-ground and below-ground pests also strongly supports a 5% interspersed infield refuge structure, as delivered by planting a seed mix refuge.

The central need for an interspersed refuge — as with any refuge strategy, is that it supports sufficient populations of susceptible target insects while enabling mixing of these insects with any resistant insects surviving in Bt corn fields. Compared with a block refuge, the novel characteristic of a seed mix is the interspersed nature of Bt and non-Bt plants within in a field. This spatial distribution will enhance the mixing of adult insects coming from Bt and non-Bt plants, ensuring that any resistant insects surviving on Bt plants will encounter susceptible insects coming from non-Bt plants, which will be beneficial for IRM. However, this spatial distribution of plants in a field also could increase the likelihood that larval insects may move between Bt and non-Bt plants because all non-Bt plants will have neighboring Bt plants. Thus, it is important to quantify the impacts of this larval movement on the refuge function within an interspersed refuge from a seed mix.

Specifically, two criteria need to be met to confirm that a 5% seed mix refuge is as effective as current refuge options for SmartStax. First, the seed mix should not lead to a biologically significant increase in sub-lethal exposure of larvae to the Bt toxins that could increase selection for Bt resistance. This could occur either through early instar larvae of the target pests moving from Bt plants to non-Bt plants after sub-lethal exposure, or by

Monsanto Company 07-CR-192E-2 Page 3 of 6

)

larvae moving from non-Bt to Bt plants as larger, more Bt-tolerant instars. Assessment of this issue requires examining the susceptibility of larvae of different ages to the proteins in SmartStax. Based on extensive data, the expectation is that the enhanced toxicity conferred by the multiple effective modes of action of SmartStax will make it unlikely that larvae will be able to move and survive in this way, particularly for the highly susceptible lepidopteran target pests. Second, the non-Bt plants in the interspersed field seed mix must support sufficient susceptible pest insects to be an adequate refuge. This can be assessed through direct surveys of pest population density on the non-Bt plants, together with appropriate mathematical modeling.

To this aim, this registration application provides data collected over the past three years assessing the efficacy and value of an interspersed 5% in-field refuge option, via a seed mix containing 5% non-Bt refuge seed + 95% SmartStax seed, as an additional refuge strategy for SmartStax corn in the U.S. Corn Belt. Details of these data and analyses are presented in Volume 2 of this submission. The supporting data and information included in this request include (1) data on Iarval movement and survival in a 5% interspersed infield refuge for the key lepidopteran (European corn borer (ECB) and southwestern corn borer (SWCB)) and coleopteran target pests (primarily western corn rootworm (WCR) and secondarily northern corn rootworm (NCR)); (2) mathematical modeling to demonstrate the acceptable risk of a interspersed 5% in-field refuge strategy compared to existing refuge strategies; (3) data on the efficacy of a 5% interspersed refuge against the target pests, and the impact of the non-Bt plants in the interspersed refuge on overall yield; (4) criteria are described for ensuring and verifying a consistent seed mix percentage during the manufacturing process; and additionally, (5) information outlining the benefits for growers, the public, and environment that would result from the addition of an interspersed refuge option for SmartStax (Volume 3 of this submission).

Presented in Volume 2, laboratory and field data indicate that a 5% seed mix will provide an effective refuge for SmartStax for ECB, SWCB, and the CRW species. For all of these pests, the non-Bt plants in a 5% seed mix consistently supported large populations of susceptible insects, while the SmartStax plants had few or no survivors. Highly conservative mathematical modeling shows that an interspersed refuge strategy will provide comparable or greater durability than 5% structured refuge in the Corn Belt, depending upon compliance with the structured refuge, and greater durability than single Bt products with a 20% refuge. Furthermore, this approach will provide yields comparable to current structured refuge systems but with greater convenience and reduced insecticide use on the refuge, thereby bringing additional benefits beyond those of SmartStax with 5% discretely structured refuge.

Presented in Volume 3, the benefits to growers, the environment, and to society at large will be realized by the addition of an interspersed 5% in-field refuge option for SmartStax. Under all 5% refuge options (the strip or block refuge strategy supported in SmartStax registrations 524-581 and 68467-7, and the interspersed 5% in-field refuge proposed with this application), SmartStax represents significant value to U.S. farmers. There are unique benefits to a SmartStax 5% interspersed refuge above those provided by discrete strip or block refuges. These include substantial non-pecuniary grower benefits, environmental

Monsanto Company 07-CR-192E-2 Page 4 of 6

benefits, and improved compliance with IRM requirements. Enabling growers to broadly plant SmartStax corn with an interspersed in-field refuge will support:

- Reduction or potential elimination of application of soil-applied insecticides
- Reduce potential for corn rootworm insecticides in ground or surface water
- Reduce farm worker exposure to organophosphate insecticides, accidental insecticide spills, and insecticide carryover effects
- Increase simplicity, flexibility, and time savings associated with planting the refuge
- Guarantee grower compliance with IRM requirements
- Provide incentive to growers to switch to pyramided Bt technology, improving durability of Bt corn technology

This request for a registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax) will allow an in-field refuge structure in which the non-Bt refuge plants are interspersed within the SmartStax field. This type of interspersed in-field refuge is a 'structured refuge', as defined by EPA (Biopesticides Registration Action Document for Bt Plant-Incorporated Protectants, October 15, 2001), and would be implemented by growers planting a defined seed mixture comprised of PIP (SmartStax) seed with a fixed amount of non-Bt (refuge) seed. In addition, this interspersed refuge would only be implemented via planting a seed-mixture manufactured by the technology provider (registrants) and appropriately licensed seed producer affiliates. This non-Bt refuge would be complementary to, but distinct from, the refuge structures currently allowed under SmartStax registrations 524-581 and 68467-7 (in-field strips, rows, or blocks).

Monsanto and Dow are hereby requesting a registration for the plant-incorporated protectant, *Bacillus thuringiensis* CrylA.105, Cry2Ab2, CrylF, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration. The interspersed refuge would be implemented via a seed mixture in bags of seed corn consisting of 5% non-Bt corn along with 95% SmartStax corn. Seed mixtures to be planted under this option would only be prepared by seed producers licensed by the registrants to ensure consistency and provide adequate refuge in the field.

The documents accompanying this request are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).

Monsanto Company 07-CR-192E-2 Page 5 of 6

 Category "C": Confidential Business Information that is protected from any disclosure indefinitely by provisions put forth by the EPA, as per FIFRA Section 10.

A CD-ROM containing the fully releasable ("A") documents in .pdf format is also provided.

It is Monsanto's understanding from communications with the EPA BPPD, that the following fee category and amount is appropriate based on the PRIA II Fee Table, effective October 1, 2008.

Fee category: B881. New Product; SAP review required

• Fee category amount: \$82,688

Documents accompanying this application for registration

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	Α	Cover letter	1	1
N/A	A	Transmittal document	1	[.√
1	A	Volume 1: Administrative volume (redacted copy)	1	1
1	В	Volume 1: Administrative volume	4	
2	В	Volume 2: Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	1	
3	В	Volume 3: The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn	1	

Should you require any additional information regarding this application please feel free to contact Dr. Russell Schneider at 202-383-2866, or myself at 314-694-6514.

Sincerely,

J. Austin Burns, Ph.D.

Regulatory Affairs Manager

Monsanto Company

cc: Mike Mendelson, EPA/OPP/BPPD Russell Schneider, Ph.D., Monsanto Dow AgroSciences, LLC 9330 Zionsville Road Indianapolis, IN 46268-1054



December 11, 2009

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attn: Dr. Keith Matthews, Esq., Director Biopesticide and Pollution Prevention Division

Subject: Letter authorizing data citation

Letter of Authorization to Refer to Regulatory Data

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "Dow AgroSciences") authorizes Monsanto Company (Monsanto) to cite, and the U.S. Environmental Protection Agency (EPA) to refer to, data previously submitted by Dow AgroSciences in connection with any of the following products:

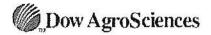
- * Insect-protected, glufosinate-tolerant maize containing the CryIF and PAT proteins, Event TC1507 (DAS-01507-1);
- Insect-protected, glufosinate-tolerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)

and all relevant data that Dow AgroSciences has provided EPA to support the Section 3 registration on MON 89034 x TC1507 x MON 88017 x DAS-59122-7, Insect-Protected, Herbicide-Tolerant Corn, EPA registration No. 68467-7, and Dow AgroSciences' pending registration for an interspersed refuge (seed mix) product using MON 89034 x TC1507 x MON 88017 x DAS-59122-7, for the purpose of evaluating and issuing a registration to Monsanto for interspersed refuge (seed mix) product using MON 89034 x TC1507 x MON 88017 x DAS-59122-7.

445

}

Dow AgroSciences, LLC 9330 Zionsville Road Indianapolis, IN 46268-1054



December 11, 2009

Document Processing Desk Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202-4501

Attn: Dr. Keith Matthews, Esq., Director Biopesticide and Pollution Prevention Division

Subject: Letter authorizing data citation

Letter of Authorization to Refer to Regulatory Data

We hereby confirm that Agrigenetics, Inc. d/b/a Mycogen Seeds c/o Dow AgroSciences LLC, on behalf of itself and its affiliates, (collectively, "Dow AgroSciences") authorizes Monsanto Company (Monsanto) to cite, and the U.S. Environmental Protection Agency (EPA) to refer to, data previously submitted by Dow AgroSciences in connection with any of the following products:

- Insect-protected, glufosinate-tolerant maize containing the Cry1F and PAT proteins, Event TC1507 (DAS-01507-1);
- Insect-protected, glufosinate-tolerant maize containing the Cry34/35Ab1 and PAT proteins, Event DAS-59122-7 (DAS-59122-7)

and all relevant data that Dow AgroSciences has provided EPA to support the Section 3 registration on MON 89034 x TC1507 x MON 88017 x DAS-59122-7, Insect-Protected, Herbicide-Tolerant Corn, EPA registration No. 68467-7, and Dow AgroSciences' pending registration for an interspersed refuge (seed mix) product using MON 89034 x TC1507 x MON 88017 x DAS-59122-7, for the purpose of evaluating and issuing a registration to Monsanto for interspersed refuge (seed mix) product using MON 89034 x TC1507 x MON 88017 x DAS-59122-7.

This authorization shall not be construed as authorization to use or consider said data, directly or indirectly, in support of any application submitted by any other applicant, for an application by Monsanto for activities other than the registration request as described herein, or for any other regulatory entity to refer to or rely on this data. Dow AgroSciences does not grant permission for citation or reference of this data for any use not specifically stated herein, does not grant permission for citation or reference of data (including future data) not specified herein, and nothing in this agreement grants permission for the U.S. EPA to provide copies of any data to any party.

If you require further information, please contact the undersigned at 317-337-3504.

Best Regards,

Laura Tagliani

1

Global Regulator Leader - Corn Traits

Lame Taylar

Dow AgroSciences LLC

There is an **ELECTRONIC LABEL** for this action

You can use Acrobat to compare the e-label to the previous version (and find the changes). You can also use Acrobat to mark-up the e-label with your comments.

If e-label was submitted via

CD-ROM with paper application

then you will find e-label in

Electronic Label Library

If the e-label is not found in the ELL then it was probably not named correctly and could not be entered into the ELL. However, the file can be retrieved from the CD which is retained by the Front End.

or

If e-label was submitted via

XML E-Submission (no paper)

then you will find e-label in

Documentum

See overview of processing e-labels on other side of this sheet.

If you have any questions on e-labels, please contact one of your division e-label experts:

AD Willie Abney 308-1689

Renae Whitaker 308-7003

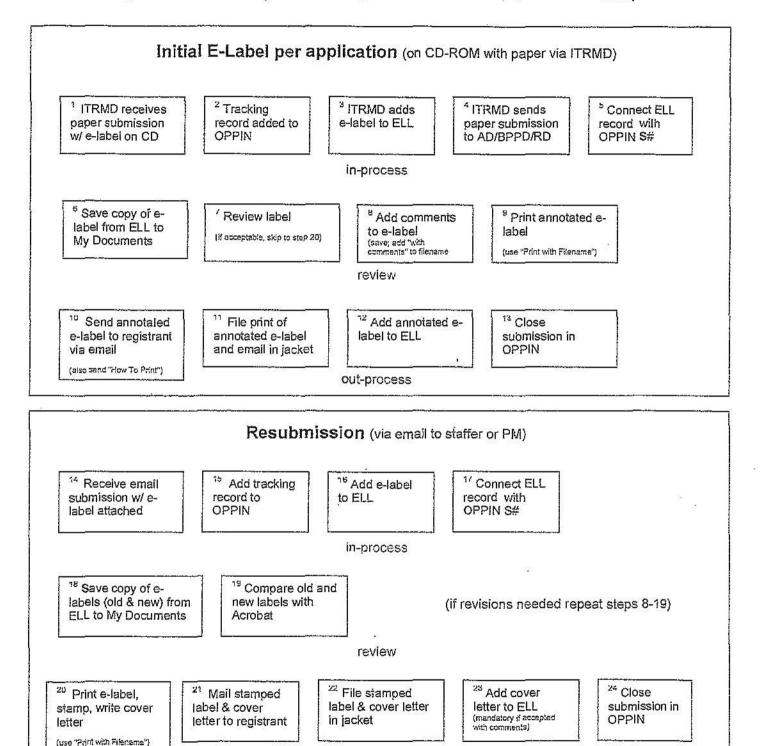
Tracy Lantz 308-6415

BPPD

RD Tom Harris 308-9423

PROCESSING ELECTRONIC LABELS

If e-label submitted via XML e-submission (not on CD-ROM), you may wish to find e-label in Documentum, save e-label to "My Documents", add e-label to ELL, start below at step 5.



out-process

process - big picture

- 1- create OPPIN tracking
- 2- put label in ELL; link to S#
- 3- save ELL label to MyDocuments
- 4- compare / comment
- 5- outprocess

techniques to know

- filename for e-labels
- "print with filename"
- compare / comment
- printing with comments

Pages 450-455

Access to FIFRA health and safety data is restricted under FIFRA section 10(g)

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with	Respect to	Citation o	f Data				
Applicant's/Registrant's Name, Address, and Telephone Number:		EPA Registration Number f File Symbol:					
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,	, MO 63167		524-XXX				
(314) 694-6514			JA I JUNE				
Active Ingredient(s) and/or representative lest con			Date:				
Bacillus thuringiensis Cryt A. 105, Cry2 Ab2, Cry1F, Cry3Bb1, Cry34Ab1 ar			December 17, 2009				
Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7	1/002) Necessar	/ tor ineir	December 17, 2009				
General Use Pattern(s) (list all those claimed for this product using 40	CFR Part 158:		Product Name:				
Terrestrial field crop			MON 89034 × TCt507 × MON 880t7 × DAS-59122-7				
NOTE: If your product is a 100% repackaging of another purchase need to submit this form. You must submit the Formulator's Exemptio							
I am responding to a Data-Call-in Notice, and have included should be used for this purpose).	with this form a	list of companie	s sent offers of compensation (the Data Matrix form				
Section I: METHOD OF DA	TA SUPPO	ORT (Check	one method only)				
I am using the cite-all method of support, and have included			selective method of support [or cite-all option under				
this form a list of companies sent offers of compensation (the			ethod), and have included with this form a				
Data Matrix Form should be used for this purpose).		used).	of dala requirements (the Oata Matrix form must be				
Section II: GE	NERAL OF	FER TO PA	AY				
[Required if using the cite-all method or when using the cite-a	all option under	the selective me	ethod to satisfy one or more data requirements[
I hereby offer and agree to pay compensation, to other perso	ns, with regard	to the approval	of this application, to the extent required by FIFRA.				
Section II	II: CERTIFI	CATION					
I certify that this application for registration, this form for reregistration for registration, the form for registration, or the Data-Camethod is indicated in Section 1, this application is supported by all data identical or substantially similar product, one or more of the ingredict under the data requirements in effect on the date of approval of this apsimilar composition and uses.	all-In response, ata in the Agend ents in this proc	In addition, if the y's files that (1) a luct; and (2) is a	e cite-all option or cite-all option under the selective concern the properties or effects of this product or type of data that would be required to be submitted				
I certify that for each exclusive use study cited In support of this registre the written permission of the original data submitter to cite that study.	ration or reregis	tration, Ihat I am	n the original data submitter or that I have obtained				
submitter; (b) I have obtained the permission of the original data sub compensation have expired for the study; (d) the study is in the publi have offered (l) to pay compensation to the extent required by sec	I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either; (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (l) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.						
I certify that in all instances where an offer of compensation is requir accordance wilh sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are ava such evidence to the Agency upon request, I understand that the Agen conformity with FIFRA.	ailable and will I	e submitted to t	the Agency upon request. Should I fail to produce				
	I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.						
Signature	Date		Typed or Printed Name and Title				
J.WVL	December 1	7, 2009	J. Austin Burns' , Regulatory Affairs Managen ,				
EPA Form 8570-34 (9-97) Electronic and Paper Versions available	e. Submit only	Paper version.					

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency,

	DA	TA MATRIX			198 155 51_225 20_0 2
Date: December 17, 2 0 09			EPA Re	g. No./File Symbol: 524-XX	X Page t of 57
Applicant's/Registrant's Name & Monsanto Company, 800 N	k Address: . Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 × 1 MON 88017 × DAS-59	7 - 1000
	nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Al r Production in MON 89034 × TC1507 × MON 88017 ×				
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Status	Note
NA	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, With an Interspersed In-Field Refuge Configuration Using a Seed Mixture		Monsanio Company	OWN	Administrative This Application
NA	Five Percent Seed Mix Refuge as an Insect Resistance Management Option for MON 89034 × TC1507 × MON 88017 × DAS-59122-7	<u></u>	Monsanto Company	OWN	Supporting Data This Application
NA	The Benefits of a 5% Interspersed In-field Refuge Option for SmartStax™ Corn		Mousanto Company	OWN	Benefits This Application
Signature	tronic and Paper versions available. Submit only Paper ve		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage		iternal Use

Сору

⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.		TAKO SA MARKA DA SA MARKA MARKA SA MARKA SA MARKA SA MARKA SA MARKA SA MARK		
	D.	ATA MATRIX			
Date: December 17, 2009				Reg. No./File Symbol: 524-581	Page 2 of 57
	Lindbergh Blvd., St. Louis, MO 63167			oduct: MON 89034 × TC1507 DAS-59122-7	420 000 000
	vsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35A Production in MON 89034 × TC1507 × MON 88017 ×				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringieusis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34 and Cry35 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7.	474449-00	Monsanto Company	OWN	Administrative
885,1100	Burns, J.A. 2008. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringicusis Cry1A.105, Cry2Ab2, Cry3Bb1, Cry1F, Cry34Ab1, and Cry35Ab1 Proteins Produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0020223.	47444901	Monsanto Company	OWN	Product Characterization
885.1100	Rice, J.F. 2008. Summary of Southern Blot Analyses to Confirm the Presence of MON 89034, TC1507, MON 88017, and DAS-59122-7 in the Combined Trait Com Product MON 89034 × TC1507 × MON 88017 × DAS- 59122-7. Monsanto Technical Report MSL0021265.	47444902	Monsanto Company	own	Product Characterization
885.1100	Taylor, J.P., J.R Groat, and J.D. Masucci. 2007. Southern Blot Analyses to Confirm the Presence of MON 89034 and MON 88017 in the Combined Trait Corn Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0020682.	47444903	Monsanto Company	OWN	Product Characterization
Signature /	in		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form\8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Monsanto Company

07-CR-192E-2

Page 21 of 175

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Oirector, OPPE information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009				EPA Reg. No./File Symbol: 524-5	581 Page 3 of 57
Applicani's/Registrant's Name & Monsanto Company, 800 N	Address: Lindbergh Blvd., St. Louis, MO 63167			Product: MON 89034 × TC1: DAS-59122	507 × MON 88017 × -7
	rsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ai Production in MON 89034 × TC1507 × MON 88017 × 1				
Guideline Reference Number	Guldeline Study Name	MRID Number	Submifler	Status	_ Note
885.1100	Schafer, B.W., C. Q. Cia, and S.K. Embrey. 2008. Southern Blot Analyses to Confirm the Presence of TCt507 and DAS-59122-7 in the Combined Trait Com Product MON 89034 × TC1507 × MON 88017 × DAS-, 59122-7. Dow AgroSciences Study ID 071179.	47444904	Monsanto Comp	any OWN	Product Characterization
885.tt00	Murphy, J.A. and J.S. McClain. 2008. Summary of CrytA. t05, Cry2Ab2, Cry1F, Cry3Bb1, CP4 EPSPS, Cry34Ab1, Cry35Ab1 and PAT Protein Levels in the Combined Trait Com Product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 Produced in US Field Trials in 2006. Monsanto Technical Report MSL0021266.	47444905	Monsanto Comp	any OWN	Product Characterization
885.tt00	Stillwell, L. and A. Silvanovich. 2007. Assessment of Cry 1A. t05, Cry2Ab2, Cry3Bbt, and CP4 EPSPS Protein Levels in the Combined Trait Corn Product MON 89034 × TC t507 × MON 88017 × DAS-59122-7. Monsanto Technicat Report MSL0021070.	47444906	Monsanto Comp	nany OWN	Product Characterization
885.1100	Phillips, A.M. 2008. Cry34Ab1, Cry35Ab1, Cry1F, and PAT Protein Levels in Hybrid Maize TCt507, DAS-59122-7, MON 89034 × TC1507 × MON 880 t7 × DAS-59122-7, and a Conventional Control from the Monsanto 2006 Production Plan 06-01-52-04. Dow AgroSciences Study tD 06t026.06.	47444907	Monsanio Comp	oany OWN	Product Characterization
Ŋ/A	Levine, S. 2008. Studies Performed to Evaluate the Potential for Interactions among Cry Proteins Produced by MON 89034 × TC1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL0021267.	47444908	Monsanio Com	any OWN	Environmental Assessment
Signature 1. A	N	3 4080 (20)	Name and Title J. Austin Bunis, Ph.D. Regulatory Affairs Ma	,	09

EPA Form-8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Monsanto Company

07-CR-192E-2

Page 22 of 175

⊕ EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	<u>D</u>	ATA MATRIX		5 - 50 - 50 - 50 - 50 - 50 - 50 - 50 -	***************************************
Dale: December 17, 2009			1	EPA Reg. No./File Symbol: 524-581	Page 4 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Ingredient Bacillus thuringtensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Ve			Genetic Materials (Vectors	Product: MON 89034 × TC1507 DAS-59122-7 PV-ZMIR245 PHP8999 PV-ZMI	
HP17662) Necessary for their DAS-59122-7)	r Production in MON 89034 × TC1507 × MON 88017 ×	DAS-59122-7 (OE	CD Unique Identifier; MON	N-89Ø34-3 × DAS-Ø15Ø7-1 × MON	N-88Ø17-3 ×
Guideline Reference Number	Guideline Study Name	MRID Number	Submiller	Status	Note
N/A	MacRae, T. 2008. Evaluation of Potential for Interaction Between the <i>Bacillus thuringiensis</i> Cry3Bb1, Cry34Ab1, and Cry35Ab1 Proteins. Monsanto Technical Report MSL0020554	4744490 9	Monsanto Compa	by OWN	Environmental Assessment
N/A	Levine, S. 2008, Evaluation of the Potential for Interactions among Cry Proteins Produced by MDN 89034 × TC t507 × MON 88017 × DAS-59122-7 by Insect Bioassay, Monsanto Technical Report MSL0021104.	47444910	Monsanto Compa	ny OWN	Environmental Assessment
N/A	Head, G. and N. Storer. 2008. Insect Resistance Management Plan for MON 89034 × TC1507 × MON 88017 × DAS-59t22-7. Monsanto Technicat Report MSL0021285.	47444911	Monsanto Compa	ny OWN	IRM
n/A	Levine, S. and J. Huesing. 2008. Endangered Species Impact Assessment for the Combined Trait Corn Product MON 89034 × TC 1507 × MON 88017 × DAS-59122-7. Monsanto Technical Report MSL002 (268.	47444912	Monsanto Compa	ny OWN	Environmental Assessment
885.4340	Paradise, M. 2008. Evaluation of Potential Dietary Effects of Pollen From the Combined Trait Corn Product MON 89034 × TCt507 × MON 880t7 × DAS-59122-7 on the Ladybird Beetle Coleamegilla maculata (Coleoplera: Coccinellidae). Monsanto Technical Report MSL 0021036.	47444913	Monsanto Compa	ny OWN	Environmental Assessment
Signature 1. A			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date December 17, 2009	

EPA Form 8570-85 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009			EPA Reg. No./File Symbol: 524-575	Page 5 of 57	
	Address: Lindbergh Blvd., St. Louis, MO 63167 ensis Cryt A.105 and Cry2 Ab2 Proteins and the Genetic	Material (Vector P		Product: MON 89034 their Production in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Status	Nole
N/A	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus fluringiensis Cryl A. t05 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MDN-89034-3).	469514 <u>-00</u>	Monsanio Compa	ny <u>O</u> WN	Administrative
885,1100	Bogdanova, N.N. 2006, Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringtensis Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.	469514-01	Monsardo Compa	ny OWN	Product Cliaracterization
885.tt00	Rice, J.F., B.J. Wolff, J.R., Groat, N.K. Scanlon, J.C. Jennings, and J.D. Musucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Com MON 89034. Monsanto Technical Report MSL-20311.	469514- <u>02</u>	Monsanto Compa	ny OWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry IA.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Compa	ny OWN	Product Characterization
885,1100	Karunanandaa, K., J.J. Thorp, M.E. Golcy, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Com Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E. coli-Produced Cry2Ab2 Proleins. Monsanto Technical Report MSL-20071.	4695 14-04	Monsanto Compa	ny OWN	Product Characterízatio
Signature J. A	97) Flectronic and Paner versions available. Submit only in	-	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man		rnal Use Copy

ERA Porm 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Oivision (2137), U.S. Environmental Protection Agency,

na sa statis en latera (1977). Est	DA	ATA MATRIX			
Date: December 17, 2009			E	PA Reg. No./File Symbol: 524-575	Page 6 of 57
Applicant's/Registrant's Name & Monsanto Company, 800 N	Address: Lindbergh Blvd., St. Louis, MO 63167		; Pi	oduci: MON 89034	
ngredlent <i>Bacillus Ihuringi</i> dentifier: MON-89Ø34-3)	ensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector PV	/-ZMIR245) Necessary for t	heir Production in MON 89034 (O	ECD Unique
Suideline Reference Number	Guldeline Study Name	MRID Number	Submitter	Stalus	Note
885.1100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in E.Coli and Br Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	469514-05	Monsanto Compan	OWN	Product Characterization
885,1100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masueci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-01	Monsanto Compan	OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lec, T. Lee, and E.A. Rice. 2005. Characterization of the Cry1A. 105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E.coli-Produced Cry1A.105 Proteins. Monsanto Technical Report MSL- 19960.	466946-04	Monsanto Compan	y OWN	Product Characterization
Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034". Supplemental Information for MRID No. 46951403 "Assessment of the Cry t A. t05 and Cry2 Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	47 1275-03	Monsanio Compan	own	Product Characterization	
	47 [275-05	Monsanto Conipan	yOwn	Product Characterization	
/	Onlic and Paper versions available. Submit only Paper vers		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana		ernal Use Copy

⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009				EPA Reg. No./File Symbot: 524-5	75 Page 7 of 57
Ingredient Bacillus thuringi	Address: Lindbergh Blvd., St. Louis, MO 63167 ensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector PV		Product: MON 89034 their Production in MON 89034	(OECD Unique
Identifier: MON-89034-3) Guldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the CrylA. 105 Protein to CrylA Class of Bacillus thuringiensis Proteins. Monsanto Technical Repon 05-RA-62-01.	466946-0t	Monsanto Compa	ny OWN	Product Claracterization
860.1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Moitsanto Coinpa	ny OWN	Product Characterization
885,3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	4695 14-06	Monsanto Compa	ny OWN	tłuman Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the in view Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	4695 t 4-07	Monsanio Compa	ny OWN	Human Health Assessment
885.1100	Kapadia, S. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the Cryl A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	4695†4-08	Monsanto Comp	nny OWN	Human Health Assessment
Signature	en		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mar	Date December 17, 200)9

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

<u> </u>	DA	TA MATRIX				
Date: December 17, 2009		EPA Reg. No./File Symbol: 524-5		24-575	Page 8 of 57	
ngredienl Bacillus thuring	Lindbergh Blvd., St. Louis, MO 63167	Product: MON 89034 or PV-ZMIR245) Necessary for their Production in MON 89034 (OECD				
dentifier: MON-89Ø34-3) Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Slatus		Note
885.1100	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cryt A. t05 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Comp	any OWN		Human Health Assessment
885.1100	Thorp, J. J. and M.E. Goley. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938	469514-09	Monsanto Comp	oany OWN		Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cryt A. 105 Protein Utilizing the AD6, TOXINS, and ALLPEPTIDES Databases. Monsanto Teclinical Report MSL-20351.	469514- <u>1</u> 0	Monsanto Comp	oany OWN		Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the Cryl A. 105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Comp	any OWN		Human Health Assessment
885,1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1 A. 105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Monsanto Comp	pany OWN		Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with Cry t A.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Comp			Human Health Assessment
Signature 0.70 Floring	CONTROL Dance Marriages available Submit only Raper you		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	nager		nal Hoo Corv

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Monsanto Company

07-CR-192E-2

Page 27 of 175

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009	8 8 9	7.		EPA Reg. No./File Symbol: 524-57	5 Page 9 of 57
	Address: Lindbergh Blvd., St. Louis, MO 63167 ensis Cry1A,105 and Cry2Ab2 Proteins and the Genetic	V-ZMIR245) Necessary (Product: MON 89034	DECD Unique	
Identifier: MON-89Ø34-3)			η	<u> </u>	
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Slatus	Note
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-11	Monsanto Comp	pany OWN	Ituman Health Assessment
885,4050	Davis, S.W. 2006. Comparison of Broiler Performance and Careass Parameters When Fed Diets Containing MON 89034, Control or Commercial Corn. Monsanto Study 05-01-50-13, Amended Report.	469514-12	Monsanto Comp	pany OWN	Human Health
NΙΛ	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of Bacillus throughersis Cryt A.105 Protein. Monsanto Technical Report MSL- 20230.	469514-13	Monsanto Com	pany OWN	Environmental Assessment
N/A	MacRac, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of Bactilus thaningiensis Cry2Ab2 Protein. Monsanto Technical Report MSL- 20229.	469514-14	Monsanto Com	pany OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, J.O. Oyediran, and T.T Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Monsanto Com	pany OWN	Environmental Assessment
Signature A. C	2001 Stackropic and Paper versions available Submit only 6		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	ападег)

EPA Form 8570-35 (9-97) Efectronic and Paper versions available. Submit only Paper version.

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	ATA MATRIX	NO 1222 CO 1222 CO 122	32 Ar 2540 577-7540 A	
Date: December 17, 2009		\[\E	PA Reg. No./File Symbol: 524-575	Page 10 of 57	
	. Lindbergh Blvd., St. Louis, MO 63167			roduct: MON 89034	
ngredient Bacillus thuringi Identifier: MON-89034-3)	ensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P)	V-ZMIR245) Necessary for	dieir Production in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (Folsomia candida). Monsanto Technical Report MSL-20169.	469514-16	Monsanto Compan	y OWN	Environmental Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran Daphnia mogna: An acute static-renewal test with compollen. Monsanto Study WL-2005-011.	469514-17	Monsanto Compan	y OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to CrytA.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.	469514-18	Monsanlo Compan	y OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A. t05 Protein on Honeybee Larvae (Apis mellifera L.). Monsanto Study CA-2005-071.	469514-19	Monsanto Compan	y OWN	Environmental Assessment
885,4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cryt A. 105 Protein on Adult Honeybees (Apis mellifera L.). Monsanto Study CA-2005-072	469514-20	Monsanto Compan	y OWN	Environmental Assessment
Signature	un-		Name and Title J. Austin Burns, Plr.D. Regulatory Affairs Mana	Date December 17, 2009 ger	

EPA Form \$570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Roduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D	ATA MATRIX			199040 - 20 0.000
Date: December 17, 2009			E	PA Reg. No./Fite Symbol; 524-575	Page 11 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			The second secon	roduci: MON 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	riensis Cry1A.105 and Cry2Ab2 Proteins and the Geneti	c Material (Vector)	V-ZMIRZ45) Necessary to	their Production in MON 89034 (O.	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885,4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cryt A.t 05 Protein on the Ladybird Beetle, Coleomegilla maculata (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20 t50.	469514-21	Monsanto Compa	ny OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, Caleomegilla maculata (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Compa	ıy OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dictary Effects of Cryl A. 105 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.	4695 t4-23	Monsanto Compa	ny DWN	Environmentat Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, Orius instdiosus (Hemiptera: Anthocondae). Monsanto Technical Report MSL-20171.	469514-24	Monsanio Compa	ny OWN	Environmental Assessment
885,4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to CrytA.105 Protein in an Acute Study with the Parasitic Wasp, <i>Iehneumon promissarius</i> (Hymenoptera: Iehneumonidae). Monsanto Technical Report MSL-20149.	469514- 2 5	Monsanto Compa		Environmental Assessment
Signature	2000-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date December 17, 2009	

EPA Folio 6570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D#	TA MATRIX			
Date: December 17, 2009			E	PA Reg, No./File Symbol; 524-575	Page 12 of 5
	Lindbergh Blvd., St. Louis, MO 63167		Pr	roduct: MON 89034	
ngredient Bacillus thuring dentificr: MON-89034-3)	iensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Necessary for	their Production in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Stalus	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dictary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain, Monsanto fechnical Report WL-2005-012.	469514-27	Monsanto Company	y OWN	Environmental Assessment
885,5200	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Company	y OWN	Environmental Assessment
n/a	Huesing, J.E., I.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Company	y OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the Bacillus Thuringiensis Proteins Cry1A. 105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	466946-02	Monsanto Company	y OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, Ichneuman promissorius (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Monsanto Company	y OWN	Environmental Assessnient
Signature /- (an		Name and Title J. Austin Burns, Pl.D. Regulatory Affairs Mana	Date December 17, 2009	

EPA Ferm 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009		5 <u>-148</u>	EP	A Reg. No./File Symbot: 524-575	Page 13 of 57
	Lindbergh Blvd., St. Louis, MO 63167		The second secon	duct: MON 89034	
Ingredient Bacillus thuring Identifier: MON-89034-3)	fensis Cry1 A.105 and Cry2 Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Necessary for t	heir Production in MON 89034 (O	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Slatus	Nole
885.4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthwonn in an Artificial Soil Substrate. Monsanto Technicat Report MSL-16177	450863-13	Monsanto Company	own	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified Bacillus thuringiensis Cry2Ab2 protein on honey bee larvae. Monsanto Technical Report MSL-t696t.	453371-02	Monsanto Company	Own	Environmentat Assessment
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (Folsomia candida), Amended report. Monsanto Technical Report MSL-16174.	450863-14	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. and H. Krueger, 2000. Insect Protection Protein 2: A Dictary Toxicity Study with Parasitic Hymenoptera (Nasomo vitripetinis). Monsanto Technical Report MSL-16173.	450863- <u>t</u> 0	Monsanto Company	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dictary Effect(s) of the three Protection Protein 2 on Adult Honey Bees (Apis mellifera L.). Monsanto Technical Report MSL-16176.	450863-08	Монѕащо Сотрапу	OWN	Environmental Assessment
Signature 1. aw		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date December 17, 2009		

EPA Form 8570(35,69-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paporwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the Instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 f37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009			EPA I	Reg. No./File Symbol: 524-575	Page 14 of 5
	Lindbergh Blvd., St. Louis, MO 63167		ect: MON 89034	3000	
ngredient Bacillus thuring dentifier: MON-89034-3)	riensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Necessary for the	r Production in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Company	OWN	IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registration of Bacillus thuringiensis CryIA, t05, Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017	4727 <u>9</u> 7-01	Monsanto Company	own	Benefits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Sitvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect- Protected Com MON 89034 (MRID 46951428)	471403-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Com MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	471275-01	Monsanto Company	OWN	Misc.
	Bogdanova, N., (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTL to Register the three three transcriptions of the three transcriptions of the three transcriptions and MON 89034 x MON 88017 (MRID 46951400 and 46951300]	470794-02	Monsanto Compairy	OWN	Misc
	onic and Paper versions available. Submit only Paper vers		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009 Agency inter	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	ATA MATRIX				
Date: December 17, 2009) EI	PA Reg. No./File Symbol: 68467-2	Page 15of 5	
Applicant's/RegIstrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				Product: Herculex® I Insect Product		
Ingledient B.r. Cry1F prote	in and the genetic material necessary for production (pl	asmid insert PIIP89	99) in maizc (OECD Identif	ier: DAS- Ø15Ø7-1)		
Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter	Slatus	Nole	
	Product Characterization Data for Bacillus thuringiensis var, aizawai Cry IF Insect Control Protein as expressed in Maize	447148-01	68467	PER		
	Characterization of Gene Inserts-Bacillus thuringiensis var, aizawai Cry IF Insect Control Proteins Expressed in Maize	447148-02	68467	PER		
	Equivalency of Microbial and Maize Expressed Cry1F Protein; Characterization of Test Substances for Biochemical and Toxicological Studies. In Vitro Digestibility of Microbial and Maize Expressed	447148-03	68467	PER		
	In Vitro Simulated Intestinal Fluid Digestibility Study of Microbially Derived CrylF (tr)	N/A	68467	PER		
	Cry F.B.t. var aizawai Delta-endotoxin: Acute Oral Toxicity Study in Mice	4469 -01	68467	PER		
Signature	onic and Paper versions available. Submit only Paper vers		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	The state of the s	nal Use Copy	

EPA Form 8570-(35 (8-97) Electronic and Paper versions available. Submit only Paper version.

⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

EPA I	Reg. No./File Symbol: 68467-2	D 15 055
		Page 16 of 57
		ection
9) in maize (OECD Identifier,	DAS- ØI5Ø7-I)	
Submitter	Status	Nole
68467	PER	
Name and Title J. Austin Burns, Ph.D, Regulatory Affairs Manager	Date December 17, 2009	
	9) in maize (OECD Identifier, Submitter 68467 68467 68467 68467 Name and Title J. Austin Burns, Ph.D.	9) in maize (OECD Identifier, DAS- Ø15Ø7-1) Submitter Status 68467 PER 68467 PER 68467 PER 68467 PER Name and Title J. Austin Burns, Ph.D.

EPA Form 8570-55 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D	ATA MATRIX			
Dale: December 17, 2009			EP.	A Reg. No./File Symbol: 68467-2	Page 17 of 57
	Lindbergh Blvd., St. Louis, MO 63167	TATE OF THE PARTY		oduct: Herculex® I Insect Prote	tection
Ingredient B.t. Cry1F prote Guideline Reference Number	in and the genetic material necessary for production (pl Guideline Study Name	MRID Number	99) in inaize (OECD Identific Submitter	er: DAS- 01507-1) Stalus	Note
	Characterizatoin of Inserted Genes in Cry IF Maize Line 1507	45020102	68467	PER	
	Characterization of Expressed Cry1F Protein in Maize Tissues (Pollen, Grain, Grain-Containing Feed, and Purified Maize-Expressed Cry1F Protein) and Microbial Expressed Cry1F Delta Endotoxin by Biological and Biochemical Procedures	45020103	68467	PER	
	Quantitative ELISA Analysis of Cry1F and PAT Expression levels in and Compositional Analysis of Maize Inbred and Hybrid Lines 1362 and 1507	45020104	68467	PER	
	Phosphinothriein acetyltransferase (PAT) protein: In Vitro Digestibility Study	4504 t 50 t	68467	PER	
, 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870 - 1870	Non-target Exposure and Risk Assessment for Environmental Dispersal of Cryl F Maize Pollen	45041502	68467	PER	
	Environmental Fate of Cryl F Protein incorporated into Soil	45020 to5	68467	PER	<u> 2</u>
Signature	Onic and Paper versions available. Submit only Paper ver		Narne and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date December 17, 2009 er AgencyInter	

EPA Form 8570-\$5 (9-97) Electionic and Paper versions available. Submit only Paper version.

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency. 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	D,	ATA MATRIX			
Date: December 17, 2009	V 661 20 2 8 8 862		l l	EPA Reg. No./File Symbol: 68467-2	Page 18 of 5
Applicant's <i>i</i> Registrant's Name 8 Monsanto Company, 8 <mark>00</mark> N	Address: . Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Prote	ection
Ingredient B.t. Cry1F prote	in and the genetic material necessary for production (planta and the genet	smid insert PHP89	99) in maize (OECD Ident	ifier: DAS-Ø15Ø7-I)	
Guideline Reference Number	Gujdeline Study Name	MRID Number	Submilter	Slatus	Nole
	Chronic Exposure of Folsomia Candida to Bacterially Expressed Cryf F Protein	45020107	68467	PER	
	B.t. Cryf F Delta-Endotoxin: A 48-Hour Static-Renewal Acute Toxicity Test with the Cladoceran (Daphria magna) Using Bacterially Expressed B.t. Cryf F Delta- Endotoxin, and Pollen from Maize Expressing B.t. Cryf F Delta-Endotoxin	45020108	68467	PER	
	Waiver Request: Fish Toxicity Text With Transgenic Maize (Corn) Containing Bacillus thuringiensis var. aizagoi (B.t.) Cry1F Delta-Endoloxin Delta-Endotoxin	4504420 l	68467	PER	
	Field Survey of Beneficial Arthropods Associated with Bacillus thuringiensis Cry IF Maize	45020113	68467	PER	
	Efficacy of Cry1F Events TC1360 and TC1507	45020114	68467	PÉR	
Signature A. A	M. Suball Control on the Control of		Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Man	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	ATA MATRIX			
Date: December 17, 2009			ļ	EPA Reg. No/File Symbol: 68467-2	Page 19 of 57
Applicant's/Registrant's Name 8 Monsanto Company, 800 N	Address: Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® I Insect Prote	ection	
Ingredient B.t. Cry1F prote	in and the genetic material necessary for production (plantage)	asmid insert PHP89	99) in maize (OECD Ident	ifier: DAS-0[507-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Cry1F Binding Studies	45020(15	68467	PER	3 <u>% 8 8 8 8</u>
	Evaluation of the Dielary Effect(s)on Honeybee Development Using Bacteriatty Expressed B.t. CrytF Delta-Endotoxin and Potten from Maize Expressing B.t. CrytF Delta Endotoxin	45041503	68467	PER	
	Cry tF Bacitlus Thuringiensis var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworn in an Articial Soit Substrate	45020106	68467	PER	
	CrytF Baciltus Thuringiensis var. Aizawai Detta Endotoxin: A Dietary Toxicity Study with Green Lacewing Larvae	45020(09	68467	PER	
	CrytF Bacillus Thuringiensis var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle	45020110	68467	PER	
Signature J. A	Onic and Paper versions available. Submit only Paper vers		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	the state of the s	nat Use Conv

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	No./File Symbol: 68467-2 Herculex® I Insect Protect	Page 20 of 57
	Herculex® I Insect Protect	
	Herculex® I Insect Protect	
ine (OECD Identifier DA		ction
aze (OECD identifier, DA	S- Ø15Ø7-1)	
Submilter	Slatus	Note
68467	PER	
tin Burns, Ph.D.	Date December 17, 2009	
	68467 68467 68467	68467 PER 68467 PER 68467 PER 68467 PER c and Title Date December 17, 2009

EPA Form 8570-35 (8-97) Electronic and Paper versions available. Submit only Paper version,

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to; Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	ATA MATRIX			
Date: December 17, 2009	0.0.1			EPA Reg. No./File Symbol: 68467-2	Page 21 of 57
Applicant's/Registrant's Name & Monsanto Company, 800 N	L Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® I Insect Prote	ection
Ingredient B.t. CryIF prote	ein and the genetic material necessary for production (plane)	asmid insert PHP89	99) in maize (OECD Ident	ifier: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guidetine Study Name	MRID Number	Submilter	Status	Note
	Supplement to MRID 44714801. Supplemental Data - Product Characterization Data for Bacillus thuringiensis var. aizawai Cry 1F Insect Control Protein as Expressed in Maize	45020117	68467	PER	
	High Dose Demonstration For Cry1F Events TC1360 and TC 1507: European Corn Boler	45131101	68467	PER	
	Toxicity of the Cry IF Protein to Neonate Larvae of the Monarch Butlerfly	45131102	68467	PER	
	Public Interest Document for Cry1F-Protected Corn (Dow AgroSciences)	45131103	68467	PER	
	Quantilative ELISA Analysis of Cryl A(b) Expression Levels in and Composition of Hybrid Lines Derived from Event 176	4513t104	68467	PER	
Signature A am		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date December 17, 2009		

EPA Form 8570-35,49-97) Electronic and Paper versions available. Submit only Paper version.

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA DA	TA MATRIX			
Date: December 17, 2009			EP/	A Reg. No./File Symbol; 68467-2	Page 22 of 57
Applicant's/Registrant's Name & Monsanto Company, 800 N	Address: . Lindbergh Blvd., St. Louis, MO 63 (67		Pro	duct: Herculex® I Insect Pro	tection
Ingredient B.t. CryIF prote	in and the genetic material necessary for production (pla	smid insert PHP89	99) in maize (OECD Identifie	er: DAS-Øt5Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Thermolatritity of Cry1F (truncated) Delta-Endotoxin	45274801	68467	PER	
	Compositional Analysis of Maize MPS Hybrid Line 1507	45274802	68467	PER	
	CrylF Lateral Flow Test Kit Procedure for Analyzing CrytF Com Grain	45279301	68467	PER	
	Method Validation Report for the Determination of Cry1F Delta-endotoxin Protein in Corn Grain by Enzyme-Linked Immunosorbent Assay	45279302	68467	PER	
	Supplement to MRID 45020109: Cry1F Bacillus Thuringiensis Var, Aizawai Delta Endotoxin: A Dietary Toxicity Study with Green Lacewing Larvae	45307801	68467	PER	
Signature Acam-		Name and Title J. Austin Burns, Ph.D. Regutatory Affairs Manage	Date December 17, 2009		

EPA Form 8570-35-(9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the Instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DA	ATA MATRIX			
		E	EPA Reg. No.JFile Symbol: 68467-2	Page 23 of 57
Address: Lindbergh Blvd., St. Louis, MO 63167		F	Product: Herculex® I Insect Prote	ction
in and the genetic material necessary for production (pla	asmid insert PHP89	99) in maize (OECD Identi	(fier: DAS-Ø15Ø7-1)	
Guideline Study Name	MRID Number	Submitter	Stalus	Note
Supplement to MRID 45020110: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle	45307802	68467	PER	
Supplement to MRID 45020111. Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenopteta	45307803	68467	PER	
Supplement to MRID 45020106: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate	45307804	68467	PER	
Supplement to MRID 45041503: Evaluation of the Dielary Effect(s) on Honeybee Development Using Bacterially Expressed Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin	45307805	68467	PER	
Supplement to MRID #45131102: Supplemental Data- High Dose Demonstration for Cry1F Events TC1360 and TC1507: European Com Borer	45307701	68467	PER	
an-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	The state of the s	
	Address: Lindbergh Blvd., St. Louis, MO 63167 in and the genetic material necessary for production (plane) Guideline Sludy Name Supplement to MRID 45020110: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle Supplement to MRID 45020111. Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenopteta Supplement to MRID 45020106: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate Supplement to MRID 45041503: Evaluation of the Dietary Effect(s) on Honeybee Development Using Bacterially Expressed Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin Supplement to MRID #45131102: Supplemental Data- High Dose Demonstration for Cry1F Events TC1360 and TC1507: European Corn Borer	Address: Lindbergh Blvd., St. Louis, MO 63167 in and the genetic material necessary for production (plasmid insert PHP89 Guideline Sludy Name MRID Number Supplement to MRID 45020110: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle 45307802 Supplement to MRID 45020111. Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenoptera 45307803 Supplement to MRID 45020106: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate 45307804 Supplement to MRID 45041503: Evaluation of the Dietary Effect(s) on Honeybee Development Using Bacterialty Expressed Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin 45307805 Supplement to MRID #45131102: Supplemental Data- High Dose Demonstration for Cry1F Events TC1360 and	Address: Lindbergh Blvd., St. Louis, MO 63167 in and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Ident Guideline Study Name MRID Number Supplement to MRID 45020110: Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle Supplement to MRID 45020111. Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenopteta Supplement to MRID 45020161. Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenopteta 45307803 68467 Supplement to MRID 45020165. Cry1F Bacillus Thuringiensis Var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate 45307804 68467 Supplement to MRID 45041503: Evaluation of the Dietary Effect(s) on Honeybee Development Using Bacterially Expressed Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin Supplement to MRID #45131102: Supplemental Data- High Dose Deuronstration for Cry1F Events TC 1360 and TC 1507: European Corn Borer Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Address: Lindbergh Blvd., St. Louis, MO 63167 Product: Herculex® I Insect Protein and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1) Guideline Sludy Name MRID Number Submitter Status Supplement to MRID 450201 to: Cry1F Baeillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Ladybird Beetle Supplement to MRID 450201 to: Cry1F Baeillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with Parasitic Hymenoptean 45307802 Supplement to MRID 4502016: Cry1F Baeillus Thuringiensis Var. Aizawai Delta Endotoxin: A Dietary Toxicity Study with the Earthworm in an Artificial Soil Supplement to MRID 4502016: Cry1F Baeillus Thuringiensis Var. Aizawai Delta Endotoxin: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate 45307804 45307804 45307805 68467 PER Supplement to MRID 45041503: Evaluation of the Dietary Effect(s) on Honeybee Development Using Baeterialty Expressed Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin and Pollen from Maize Expressing Bt Cry1F Delta-Endotoxin Supplement to MRID #45131102: Supplemental Data- High Dose Denonstration for Cry1F Events TC1360 and TC1507: European Com Borer Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager

EPA Form 8570-85 (8-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paporwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D,	ATA MATRIX			
Date: December 17, 2009				PA Reg. No./File Symbol: 68467-2	Page 24 of 57
Applicant's/Registrant's Name & Monsanto Company, 800 N.	Lindbergh Blvd., St. Louis, MO 63167	Product: Herculex® I Ins			
Ingredlent B.t. Cryl F prote	in and the genetic material necessary for production (pl	asmid insert PHP89	99) in maize (OECD Identi	fier: DAS-Ø15Ø7-1)	
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Status	Note
	Waiver Request: Fish Toxicity Text to Assess the Potential Effects of Maize Containing Bacillus thuringiensis var. aizawai (Bt) CrytF Insecticidal Crystal Protein (ICP) on Native Fish	45307702	68467	PER	
	Supplement to MRID 4513t103: Supplemental Data Public Interest Document for Cry 1F-Protected Com (Dow AgroSciences L.L.C.)	45301101	68467	PER	
	Exposure and risk assessment of Herculex*t Bt field corn pollen to the Karner blue butterfly	455†2901	68467	PER	
	Nutritional equivalency of B.t. Cry1F maize-poultry feed	45622001	68467	PER	
	Field Survey of Beneficial Arthropods Associated with Bacillus thuringiensis CrytF Maize	45648001	68467	PER	
Signature	m-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date December 17, 2009	

EPA Form 8570-35-(9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 f37), U.S. Environmental Protection Agency, 401 M Streel, S.W., Washington, DC 20460. Do not send the form to this address.

DA	TA MATRIX			5200 52
	E	EPA Reg. No./File Symbol: 68467-2		
Address: Lindbergh Blvd., St. Louis, MO 63167	P	tection		
in and the genetic material necessary for production (pla	sınid insert PHP89	99) in maize (OECD Identif	ier: DAS-Ø15Ø7-I)	
Guideline Study Name	MRID Number	Submilter	Status	Nole
Field Surveys of Non-Target Invertebrate Populations in Bt Corn	45652001	68467	PER	
Development and Characterization of Enzyme Linked- tmmunosorbent Assay (ELISA) for Detection of Cry1F Protein	45685601	68467	PER	
tndependent Laboratory Validation of Method GRM 02.13, Determination of Cry1F delta-Endotoxin Protein in Com Grain by an Enzyme Linked Immunosorbent Assay	45685602	68467	PER	
Supplemental to MRID 45131102: Toxicity of the Cry! F Protein to Neonate Larvae of the Monarch Butterfly	45759701	68467	PER	
Stewardship of Herculex I (PIP) Label with Respect to the Secondary Lepidopleran Pest Western Bean Cutworm (Richia Albigosta Smith)	45885501	68467	PER	
w		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date December 17, 2009 ger	
	Address: Lindbergh Blvd., St. Louis, MO 63167 in and the genetic material necessary for production (plated of the genetic material necessary for production of the genetic material for the genetic mat	Lindbergh Blvd., St. Louis, MO 63167 in and the genetic material necessary for production (plasmid insert PHP89 Guideline Study Name MRID Number Field Surveys of Non-Target Invertebrate Populations in Bt Corn 45652001 Development and Characterization of Enzyme Linked-tumnunosorbent Assay (ELISA) for Detection of Cry1F Protein 45685601 Independent Laboratory Validation of Method GRM 02.13, Determination of Cry1F delta-Endotoxin Protein in Corn Grain by an Enzyme Linked Immunosorbent Assay 45685602 Supplemental to MRID 45131102: Toxicity of the Cry1F Protein to Neonate Larvae of the Monarch Butterfly 45759701 Stewardship of Herculex I (PIP) Label with Respect to the Secondary Lepidopteran Pest Western Bean Cutworm	Address: Lindbergh Blvd., St. Louis, MO 63167 in and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identification of Study Name MRID Number Submilter Field Surveys of Non-Target Invertebrate Populations in Bt Corn Development and Characterization of Enzyme Linked-tempunososibent Assay (ELISA) for Detection of Cry1F Protein Development Laboratory Validation of Method GRM O2.13, Determination of Cry1F delta-Endoloxin Protein in Corn Grain by an Enzyme Linked Immunosorbent Assay 45685602 68467 Supplemental to MRID 45131102: Toxicity of the Cry1F Protein to Neonate Larvae of the Monarch Butterfly Stewardship of Herculex I (PIP) Label with Respect to the Secondary Lepidopleran Pest Western Bean Cutworm (Richia Albicosta Smith) Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana.	Address: Lindbergh Blvd., St. Louis, MO 63167 In and the genetic material necessary for production (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1) Guideline Study Name MRID Number Submilter Status Field Surveys of Non-Target Invertebrate Populations in Bt Corn Development and Characterization of Enzyme Linked-timunosoribent Assay (ELISA) for Detection of Cry1F Protein thidependent Laboratory Validation of Method GRM 02.13, Detenuination of Cry1F delia-Endoloxin Protein in Corn Grain by an Enzyme Linked Immunosorbent Assay Supplemental to MRID 45131102: Toxicity of the Cry1F Protein to Neonate Larvae of the Monarch Butterfly Stewardship of Herculex I (PIP) Label with Respect to the Secondary Lepidopteran Pest Western Bean Cutworm (Richia Albieosta Smith) Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009			EP	A Reg. No./File Symbol: 68467-2	Page 26 of 5
Applicant's/Registrant's Name &					
	Lindbergh Blvd., St. Louis, MO 63167			duct: Herculex® I Insect Prote	ection
ngredient B.t. Cry1F prote	in and the genetic material necessary for production (pla	smid insert PHP89	99) in maize (OECD Identifi	er: DAS-Ø15Ø7-1)	
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Slewardship of Herculex I with respect to the secondary tepidopteran pests lesser comstalk borer (Elasmopalpus lignosellus, Zeller), southern corn stalk borer (Diatraea crambidoides, Grote) and sugarcane borer (Diataea saccharalis, Fabricius)	46600201	68467	PER	
	Slide Presentation Summarizing European Corn Borer and Cry IF Resistance Monitoring Updale	4669580 t	68467	PER	
	Researh Results on 2004 European Corn Borer Collection from Hamilton County, Iowa	4701 1201	68467	PER	
	Soil Accumulation of Cry IF Protein after Three Years of Cropping with Herculex	47120701	68467	PER	
	TC1507 Maize and Fall Armyworm in Puerto Rico	4717600 t	68467	PER	
Signature	an	X. 98 10 18	Name and Title J. Austin Burns, Ph.D. Regulalory Affairs Manag	Date December 17, 2009	

◆EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

VE NO. 10 10 NO. 10 10		ATA MATRIX			
Date: December 17, 2009		EPA	EPA Reg. No./File Symbol: 524-551 Pe		
Applicant's/Registrant's Name & Monsanto Company, 800 N	Address: Lindbergh Blvd., St. Louis, MO 63167	Prod	Product: MON 88017		
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production i	n event MON 88017 com (OEC	D Unique Identifier: MON-8801	(7-3).
Guideline Reference Number	Guldeline Study Name	MRIO Number	Submitter	Status	Note
885.1100	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cry3Bb1 Protein Produced in MON 88017. MSL-18835	-461817-01	Monsanto Company	own	Product Characterization
885.1100	Beasley, K. A., H.M. Anderson., P.B. Wimberley, D.W. Mittank., and R.P. Lirette. (2002). Molecular analysis of YieldGard*Rootworm/Roundup Ready*Com Event MON 88017. MSL-17609	461817-02	Monsanto Company	OWN	Product Characterization
885.1100	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bbt and CP4 EPSPS Protein Levels in Com Tissues Collected from MON 88017 Com Produced in U.S. Field Trials Conducted in 2002. MSL-18823	461817-0 <u>3</u>	Monsanto Company	OWN	Product Characterization
885.1100	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of Functional Equivalence of Two Cry3Bbl Protein Variants Against Susceptible Coleopteran species. MSL-18799	461817-04	Monsanto Company	<u>o</u> wn	Product Characterization
885.t 100	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bbt Protein Produced in MON 863. MSL-17137	454 2 40-t0	Monsanto Company	OWN	Product Characterization
	97) Electronic and Paner versions available. Submit only	·	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana		rnal Use Copy

EPA Form 8870-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, OC 20460. Do not send the form to this address.

	D/	ATA MATRIX			
Date: December 17, 2009			EF	A Reg. No./File Symbol: 524-551	Page 28 of 5'
	Lindbergh Blvd., St. Louis, MO 63167	Product: MON 88017			
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OI	ECD Unique Identifier: MON-880	17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001). Characterization and Equivalence of the Cry3Bbt Protein Produced by E. coli Fermentation and MON 863. MSL-17274	455382-01	Monsanto Company	OWN	Product Characterization
860.1340	Brown, M. (2003). TrairCliek TM Cry3Bb Lateral Flow Test Strip and SeedChek TM Cry3Bb ELtSA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategics Diagnostics, Inc.	463942-01	Monsanto Company	OWN	Produci Characterizalion
885.1100	Dudin, Y. A., B-P. Tonnu, L. D. Albee and R. P. Lirette (2001). Amended Report for MSL-16559: B.r. Cry3Bb1.11098 and NPTH Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. MSL-17181	454240-01	Monsanto Company	, OWN	Product Characterization
885.1100	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bbt Protein Variants Against Susceptible Colcopteran Species" (MRtD No. 461817-04)	465783-03	Monsanto Company	, OWN	Product Characterization
885.1100	Thoma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bbt.t1098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154	454240-†!	Monsanto Company	, OWN	Product Characterization
700	and Paper versions available. Submit only Paper vers		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man		rnal Use Conv

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	ATA MATRIX			
Date: December 17, 2009			EF	PA Reg. No./File Symbol: 524-551	Page 29 of 57
	. Lindbergh Blvd., St. Louis, MO 63167			oduct: MON 88017	
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production is	n event MON 88017 com (O	ECD Unique Identifier: MON-880	17-3)
Guldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885,1100	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863: Com Rootwonn Protected Com (Vector ZMIR13L); EPA File Symbol 524-LEI.	N/A_	Monsanto Company	OWN	Product Characterization
885.1100	Dudin, Y., B-P. Tonnu and R. P. Lirette (2001), Cry3Bb1, Cry1Ab and NPTII Protein Levels in the Dual- traft Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. MSL-17266	457917-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of B.t. Protein 11098, B.r. Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources. MSL-17222	454240-04	Monsanto Company	, OWN	Product Characterization
885,1100	Supplemental Information for "Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	Monsanto Company	OWN	Product Characterization
885.1100	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Corn Event MDN 863 to Microbial Sources. MSL-17220	454240-05	Monsanto Company	OWN	Product Characterization
Signature	97) Electronic and Paner versions available. Submit only		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mai		rna! Use Conv

EPA Form-6570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	n, DC 20460. Do not send the form to this address.	ATA MATRIX			
Date: December 17, 2009			EPA	Reg. No./File Symbol: 524-551	Page 30 of 57
Applicant's/Registrant's Name 8 Monsanto Company, 800 N	Address: Lindbergh Blvd., St. Louis, MO 63167			uct: MON 88017	
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production i	n event MON 88017 com (OEC	D Unique Identifier: MON-88Øt	7-3)
Guideline Reference Number	Guideilne Study Name	MRID Number	Submitter	Status	Note
885.tt00	Supplemental Information for "Motecular Analysis of YieldGard® Rootworn/Roundup Ready® Corn Event MDN 88017" (MRID No. 461817-02)	465783-01	Monsanto Company	own	Product Characterization
860.1340	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	Monsanto Company	OWN	Product Characterization
N/A	Astwood, J. D., R. E. Hiteman, M. J. McKee, T. J. Rydd, J. W. Seale and L. English (2001). Safety Assessment of Cry3Bbt Variants in Corn Rootworm Protected Corn. MSL-17225	454240-09	Monsanto Company	DWN	Human Health Assessment
885.1100	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the in vitro Digestibility of Cry3Bbt.t1098(Q349R) Protein in Simulated Intestinat Fluid. MSL-17530	455770-02	Monsanto Company	OWN	Human Health Assessment
885.1100	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bbt.t1098 and Cry3Bbt.t123t Proteins in the Grain of Insect Protected Com Events MON 863 and MON 853 After Heat Treatment. MSL-17223	454240-07	Monsanto Company	DWN	tIuman Health Assessment
7-0	27) Stoctronic and Paper versions available. Submit only		Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Mana	Date December 17, 2009 ger	

EPA Ferm 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	b/	ATA MATRIX			
Date: December 17, 2009				EPA Reg. No./File Symbol: 524-551	Page 31 of 57
Applicant's/Registrant's Name 8		30 320			
	Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017	
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production i	n event MON 88017 com (OECD Unique Identifier: MON-886	017-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Slatus	Note
885.3050	Bechtel, C. L. (1999). Acute Oral Toxicity of B.r. Prolein (1231 in Mice. MSL-16216.	449043-05	Monsanto Compa	iny OWN	Human Health Assessment
885.1100	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases. MSL-17140	454240-08	Monsanto Compa	any OWN	Human Health Assessment
885,3050	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with E. coli Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Repon. MSL-17382	455382-02	Monsanto Comp	any OWN	Human Health Assessment
885,1100	Leach, J. N., R. E. Hileman and J. D. Astwood (2001). Assessment of the <i>in vitro</i> Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from E. coli. MSL-17292	455382-03	Monsanto Compa	any OWN	Human Health Assessment
885,3050	Bechtel, C. L. (1999). Acute Oral toxicity of B.r. Protein 11098 in Mice. MSL-16215	449043-06	Monsanto Comp	·····	Human Health Assessment
Signature	Cem-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M		ornal Mag Cant

EPA Forth 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009			E	PA Reg. No./File Symbol: 524-551	Page 32 of 57
Applicant's/Registrant's Name 8 Monsanto Company, 600 13	Address: 3 th Street, N.W., Suilc 66 0 , Washington, D.C. 2000:	5	Pı	roduct: MON 88017	
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (O	ECD Unique Identifier: MON-88Ø1	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Status	Nole
885.1100	1tileman, R. E. and J. D. Astwood (†999). Bioinformatics Analysis of B.t. Prolein †1098 and B.r. Protein †1231 Sequences Utilizing Toxin and Public Domain Genetic Databases. MSL-15870	449043-08	Monsanto Compan	y OWN	Human Health Assessment
885.1100	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of B.I. Protein † 1098 and B.I. Protein 1123† Sequences Utilizing an Allergen Database. MSL-15873	449043-09	Monşanto Compan	y OWN	Human Health Assessment
885,1100	Lcach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the In Vitro Digestibility of B. r. protein t 1098 and B. r. 11231 Utilizing Mammalian Digestive Fale Models. MSL-17166	454240-06	Monsanto Compan	y OWN	Hurnan Health Assessinent
885.4200	McKee, M. J. (2001). Bluegilt Dietary Toxicity Study for the Bacillus thuringiensis Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383	455382-00	Monsanio Compan	y OWN	Environmental Assessment
885.4240 Series 72, Subdivision E	Drottar, K. R. and H. O. Krueger (1999). Bacillus duringiensis Protein †1098 in Com Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (Daplonia magna). MSL-16163	449043-18	Monsanto Compan		Environmental Assessment
Signature	ON Floritonic and Paper Versions quallable Submit only		Name and Title J. Austin Burns, Ph.D., Regulatory Affairs Ma	The second secon	rnal Use Conv

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D,	TA MATRIX			
Date: December 17, 2009			EPA	Reg. No./File Symbot: 524-551	Page 33 of 57
	Lindbergh Blvd., St. Louis, MO 63167	465 355 G		duct: MON 88017	
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OE	CD Unique Identificr: MON-8801	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Slatus	Nole
885.4280	Results of acute toxicity tests with Daphnia and catfislidid not produce any evidence of adverse effects. Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Texiera, D. (2005). Evaluation of Dietary Effects of a Cry3Bb I Protein Variant on Minute Pirate Bugs (Orins institutiosis). MSL-19697	464799-05	Monsanto Company	own	Environmental Assessment
885.4300	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4340	Patmer, S. J. and H. O. Krueger (1999). Bacillus thoring iensis Protein 11231. Dictary Toxicity Study with the Ladybird Beetle (Hippodomia convergens). MSL-16166	449043-14	Monsanto Company	OWN	Environmental Assessment
850,6200	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999). Boeillus thuringiensis Protein 11231 An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162	449043-16	Monsanto Company	OWN	Environmental Assessment
Signature	OTI Electronia and Based Versiens available. Submit calv		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Oo not send the form to this address.

40 1 M Street, S.VV., VVasningtor	n, DC 20460. Oo not send the form to this address.	ATA MATRIX			
Date: December 17, 2009			EPAI	Reg. No./File Symbol; 524-551	Page 34 of 57
	Lindberglt Blvd., St. Louis, MO 63167			ect: MON 88017	
ingredient B.f. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	n event MON 88017 com (OEC	D Unique Identifier: MON-88Ø1	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Slatus	Nole
885.4340	Teixeira, D. (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the Bacillus uturingiensis Protein 11098 to Collembola (Folsomia candida). MSL-15988	449043-17	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). Bocillus thuringiensis Protein 11231. A Dietary Study with Green Lacetving Larvae (Chrysaperla carnea). MSL-16165	449043-12	Monsanto Company	OWN	Environmental Assessment
885.4340	Palmer, S. J. and H. O. Krueger (1999). Bacillus thuringiensis Protein 11231. A Dietary Study with the Parasitic Hymenoptera (Nasonia vitripennis). MSL-16167	449043-13	Monsanto Company	OWN	Environmental Assessment
885.5200	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bbt Protein in Corn Fields Planted with MON 863. MSL-19285	465103-01	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dictary Effects of Transgenic Bocillus thuringlensis (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, Coleonegilla maculata. MSL-16936	<u>453613-01</u>	Monsanto Company	OWN	Environmental Assessment
Signature	97) Electronic and Paner versions available. Submit only		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag		na! Use Copy

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of informallon is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	TA MATRIX			
Dale: December 17, 2009	9			EPA Reg. No, IFile Symbol: 524-551	Page 35 of 5
Applicant's/Registrant's Name &					
	Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017	
	ein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OECD Unique Identifier: MON-880	17-3)
Guideline Reference Number	Guideline Study Name	MRIO Number	Submilter	Slatus	Nole
885.4340	Bryan, R. L., I. R. Porch and H. O. Krueger (2001). Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bbt Protein on the Ladybird Beetle, Hippadamta convergens. MSL-17171	453613-02	Monsanto Compa	ny OWN	Environmental Assessment
154-3500	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2004). Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179	455382-06	Monsanlo Compa	iny OWN	Environmental Assessment
885,4340	Duan, J. J., M. J. McKee and T. E. Nickson (2001). Dictary Effects of Transgenic Bacillus thuringiensis (B1) Com Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, Coleomegilla maculata. MSL-16907	455382-04	Monsanto Compa	my OWN	Environmental Assessment
885.4340	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bbt Variant Protein to First Instar Monarch Butterfly Larvae (Danus plexippus) via Laboratory Bioassay. MSL-17235	455382-05	Monsanto Compa	iny OWN	Environmental Assessment
N/A	Head, G., M. Pleau, S. Sivausupramanian and T. Vaughn (2001). Insecticidal Spectrum of Activity for Cry3Bb Protein in vitro. C3NTO	455382-07	Monsanto Compe	iny OWN	Environmental Assessment
Signature	en		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date December 17, 2009	

EPA/Eorm 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, OC 20460. Do not send the form to this address.

	D	ATA MATRIX			
Date: December 17, 2009			EPA	Reg. No./File Symbol: 524-551	Page 36 of 5
Applicant's/Registrant's Name & Monsanto Company, 800 N.	Address: Lindbergh Blvd., St. Louis, MO 63167		Prod	luct: MON 88017	
ngredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZM1R39) necessary	for its production in	n event MON 88017 com (OEC	D Unique Identifier: MON-88Ø	17-3)
Guideline Reference Number	Guideline Sludy Name	MRIO Number	Submilter	Slatus	Note
N/A	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. MSL-17614	455770-03	Monsanto Company	OWN	Environmental Assessment
154-2300	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nonlarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7	456530-03	Monsanto Company	OWN	Environmental Assessment
154-3500	Bliatti, M. A., J. D. Duan, C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Roolworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report MSL-17531	457916-01	Monsanto Company	OWN	Environmental Assessment
850.6200	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137	457571-01	Monsanto Company	OWN	Environmental Assessment
885.4050	Gallagher, S. P., J. Grimes and J. B. Beavers (1999). Bacillus theringiensts Protein † 1231 in Corn Grain: A Oietary Toxicity Study with the Northern Bobwhite. MSL-16161	449043-1 <u>5</u>	Monsanto Company	OWN	Environmental Assessment
Signature	an		Name and Title J. Austin Burns, Ph.D., Regulatory Affairs Mana	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Oirector, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, OC 20460. Do not send the form to this address.

		ATA MATRIX			
Date: December 17, 2009				PA Reg. No./File Symbol: 524-551	Page 37of 5
	. Lindbergh Blvd., St. Louis, MO 63167			roduct: MON 88017	
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	n event MON 88017 com (C	ECD Unique Identifier. MON-880	17-3)
Suideline Reference Number	Guideline Study Name	MRIO Number	Submitter	Status	Note
885.4380	Maggi, V L. (1999). Evaluation of the Dietary Effect(s) of Purified Bacillus inuringiensis Protein 11231 on Adult Honey Bees (Apis mellifera L.). MSL-16169	449043-11	Monsanto Compan	y OWN	Environmental Assessment
885.5200	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudjn (2000). Aerobic Soil Degradation of the B.r. Protein 11098 as a Component of Insect Protected Com. MSL-16440	451568-04	Monsanto Compan	y OWN	Environmental Assessment
885.5200	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry3Bbt Variant Protein Produced in Corn Rootworm Protected MON 863. MSL-17102	457571-02	Monsanto Compan	y OWN	Environmental Assessment
885,4050	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459415-01	Monsanto Compan	y OWN	Environmental Assessment
885,4380	Moggi, V.L. (1999). Evaluation of the Dictary Effects of Purified Bacillus illuringiensis Protein 1231 on Honey Bee Larvac. MSL-16168	449043-10	Monsanto Compan	y OWN	Environmental Assessment
885,5200	Dubelman, S., B. Ayden, J. Colyer, B. Ledesma, S. Levine, F. Lloyd, G. Mueller, J. Warren & C. Jiang (2007) Environmental Fate of the Cry3Bbt and Cry1Ab Proteins in Corn Fields Planted with MON 863 x MON 810 for Three Consecutive Years MSL-20589	472829-02	Monsanto Compan	y OWN	Environmental Assessment
Signature	97) Electronic and Paper versions available, Submit only		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		erna! Use Copy

€EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the Instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	ATA MATRIX			
Date: December 17, 2009			EP/	A Reg. No./File Symbol: 524-551	Page 38 of 57
	. Lindbergh Blvd., St. Louis, MO 63167			duct: MON 88017	
Ingredient B.I. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OE	CD Unique Identifier: MON-880	17-3)
Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter	Status	Note
154-3500	Duan, J., M. Bhatti, C. Brown, G. Head, C. Jiang, C. Pilcher, C. Pilcher, D. Carson & T. Niekson (2007) Two Year Field Assessment of the Effect of Combined Trait Bt Corn Mon 863 x MON 810. MSL-19696	472 <u>82</u> 9-0t	Monsanto Company	OWN	Environmental Assessment
t54-3500	Duan J. J., C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Corn Event MON 863. MSI-19246	462627-03	Monsanto Company	ÓWŅ	Environmental Assessment
154-3500	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Nickson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Corn Event MON 863. MSL-19329	463942-02	Monsanto Company	OWN	Environmentat Assessment
885,5200	Dubelman S., M. Bhatti and B. Ayden (2004). Interim Report: Assessment of the Environmental Fate of the Cry3Bb t Protein in Corn Fields Planted with MON 863. MSL-1893 t	462001-01	Monsanto Company	OWN	Environmentat Assessment
885.4340	Duan J. and M. Paradise (2005). Evatuation of Dietary Effects of Cry3Bbt Protein on the Ground Beetle Poecitus chalcites (Colecoptera:Carabidae). MSL-19631	464799-04	Monsanto Company	OWN	Environmental Assessment
t54-3500	Head, G. (2004). Research on the Effects of Corn Rootworm Protected Transgenic Corn on Non-Target Organisms; Publications & Manuscripts.	462627-02	Monsanto Company	<u>own</u>	Environmental Assessment
Signature	97) Electronic and Paper versions available. Submit only l		Name and Title J. Austin Bums, Ph.D Regulatory Affairs Mana		ernal Use Conv

EPA Form 8870-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notico: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	DA	ATA MATRIX			
Date: December 17, 2009			EPA F	eg. No./File Symbol: 524-551	Page 39 of 57
Applicaril's/Registrant's Name & Monsanto Company, 800 N.	Address: Lindbergh Blvd., St. Louis, MO 63167		Produ	ot: MON 88017	
Ingredient B.f. Cry3Bb1 prote	ein and the genetic material (vector ZMIR39) necessary	for its production i	n event MON 88017 com (OECI	Unique Identifier: MON-880	17-3)
Guideline Reference Number	Guideline Sludy Name	MRID Number	Submitter	Slatus	Nole
885.4150	Mammalian wildlife exposure to Cry3Bbt protein is considered likely; however, the Cry3Bbl toxicity data for Human Health Assessment indicate that there is no significant toxicity to rodents form testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N/A	Monsanto Company	OWN	Environmental Assessment Waived in BRAD
885.4200	Li, M. H. and E. H. Robinson (1999). Evaluation of the three transcet Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164	449043-19	Monsanto Company	OWN	Environmental Assessment
885.4340	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Data Waiver Request: Toxicity of B.t. Cry3Bbt Protein in the Red Milkweed Beetle (Tetraopes sp.). MSI-18741	N/A	Monsanto Company	OWN	Environmental Assessment Granted in BRAD
N/A	Pileher, C. D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3	453613-03	Monsanto Company	OWN	Benefits
N/A	Mitchell, P. D. (2002). Yield Benefit of MON 863. MSL-17782	456530-02	Monsanto Company	OWN	Benefits
Signature	an		Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Manag	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version,

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	D.	ATA MATRIX			
Date: December 17, 2009			EPAI	Reg. No./File Symbol: 524-551	Page 40 of 5
	. Lindbergh Blvd., St. Louis, MO 63167		Produ	ct: MON 88017	
Ingredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OECI	Unique Identifier: MON-88@t	7-3)
Guideline Reference Number	Guldeline Study Name	MRID Number	Submilter	Status	Note
N/A	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of Bacillus thuringiensis Cry3Bb1 Protein and the Genetic Material (Vector ZMIR I3L) Necessary for its Production in MON 863. MSL-17766	456530-01	Monsanto Company	OWN	Benefits
N/A	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, Bocillus thuringiensis Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E	450297-01	Monsanto Company	OWN	Benefits
N/A	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Com Rootworm Resistant Varietal Technology - YieldGard® Rootworm. MSL-17993	456923-01	Monsanto Company	OWN	Benefits
N/A	Vaughn, T. T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootwarm Species, Northern Corn Rootworm (Diobratica borberi), Southern Corn Rootworm (D. undecimpunctato howardi), and Western Corn Rootworm (D. virgifera virgifera). MTC RPT4	455382-08	Monsanto Company	OWN	Benetīts
N/A	Vaughn, T., D. Ward, J. Persliing, G. Head and J. McFerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Centrol Product. MSL-17556	455770-01	Monsanto Company	OWN	Benefits/IRM
Signature	an		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date December 17, 2009 er	

EPA Form 8570-35-(9-97) Electronic and Paper versions available. Submit only Paper version.

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	D/	ATA MATRIX			
Date: December 17, 2009			EP	A Reg. No./File Symbol: 524-551	Page 41 of 5
······································	. Lindbergh Blvd., St. Louis, MO 63167	6. 11		oduci: MON 88017	
Guideline Reference Number	ein and the genetic material (vector ZMIR39) necessary Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T Vaughn (2004). Progress Report on Insect Resistance Management for Corn Event MON 863.	461865-01	Monsanto Company	OWN	lRM_
N/A	Vaughn, T. (2001). Preliminary Results of Research on Insect Resislance Management for a Transgenie Corn Rootworm Control Product.	453484-01	Monsanto Company	OWN	IRM
N/A	Head, G. and K. Reding. (2006). Corn rootworm toseco Resistance Management Research (fourteen journal publications)	467424-01	Monsanto Company	OWN	IRM
N/A	Davis, P., G. Head, J. McFerson et. al. (2000). Insect Resistance Management for a Transgenic Com Rootworm Control Product.	<u>451568</u> -05	Monsanto Company	OWN	IRM
N/A	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	Monsanto Company		_IRM
	2000 Spectronic and Paner versions available. Submit only		Name and Title J. Auslin Burns, Ph.D., Regulatory Affairs Man	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D _A	ATA MATRIX			
Date: December 17, 2009			E	PA Reg. No./File Symbol: 524-551	Page 42 of 57
	Lindbergh Blvd., St. Louis, MO 63167			roduct: MON 88017	
	ein and the genetic material (vector ZMIR39) necessary		n event MON 88017 com (O	ECD Unique Identifier: MON-88Ø	17-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	T. Vaughn (2005). Second Progress Report on Insect Resistance Management for Corn Event MON 863. REVISED	N/A	Monsanto Compan	y OWN	1RM
N/A	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the corn rootworm pest complex.	N/A	Monsanto Compan	y OWN	IRM
N/A	Vaughn, T. (2004). 2004 Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	Monsanto Compan	y OWN	IRM
N/A	Administrative Materials in Support of the Registration of Bocillus thuringiensis Cry3Bb Protein and the Genetic Material (Vector ZMIR t3L) Necessary for its Production in Com; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	45t568-00	Monsanto Compan	y OWN	Toterance Exemption
N/A	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant Bocillus thuringiensis Corn Rootwonn Control Protein, as Produced in the Corn (Zeaa mays, L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	Monsanto Compan	y OWN	Tolerance Exemption
Signature	27) Slackronic and Paper versions available. Submit only		Name and Title J. Austin Burns, Ph.D., Regulatory Affairs Ma	Date December 17, 2009	arnal Hea Conv

EPA Pour 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕ EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paporwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	DA	ATA MATRIX			
Date: December 17, 2009]:	EPA Reg. No./File Symbol: 524-551	Page 43 of 5
Applicant's/Registrant's Name 8		7,100			
	. Lindbergh Blvd., St. Louis, MO 63167			Product: MON 88017	
ngredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	n event MON 88017 com (OECD Unique Identifier: MON-880	17-3)
Suideline Reference Number	Guldeline Study Name	MRID Number	Submitter_	Slatus	Note
N/A	Petition for Exemption from the Requirement of a Tolerance for Bacillus thuringicnsis Cryt, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	Monsanto Compa	iny OWN	Tolerance Exemption
885.1100	McCoy, R. L. and A. Sivanovich (2003). Bioinformatics Analysis of the CP4 EPSPS Protein Utilizing the AD4, TOXINS and ALLPEPTIDES Databases. MSL18752	466361-01	Monsanto Corapa	ny OWN	Inert Ingredient
885.1100	McCoy, R.L. and A. Sivanovich (2005). Updated Bioinformatics Evaluation of the CP4 EPSPS Protein Utilizing the AD5 Database. MSL19894	466361-02	Monsanto Compa	iny OWN	Incrt Ingredient
885.3050	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient. Transmittal of 1 Study.	436919-00	Monsanto Compa	iny OWN	lnert Ingredient
885.3050	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgette (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12: 92-419-719	436919-01	Monsanto Compa	ury OWN	Inert tngredient
Signature	an-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, Most Street, S.M. Washington, DC 20460. Do not send the form to this address.

	D/	TA MATRIX			
Date: December 17, 2009			le le	PA Reg. No./File Symbol: 524-551	Page 44 of 5
Applicant's/Registrant's Name &					~ \ <u> </u>
	Lindbergli Blvd., St. Louis, MO 63167			roduct: MON 88017	
	ein and the genetic material (vector ZMIR39) necessary	The second second second second second			
uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Stalus	Note
885.1100	Padgette, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-Enolpyruvylskinate-3-phosphate Synthase from Agrobocterium sp. Strain CP4. MSL-12738	438076-01	Monsanto Compar	y OWN	Inert Ingredient
885.1100	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant Escherichia coli Fermentation. MSL- 12389	438076- <u>02</u>	Monsanto Compan	y DWN	Inert Ingredien
885. t100	Heeren, R., S. Padgette and M. Gustafson (1993). The Purification of Recombinant Escherichia coli CP4 5-enolypyruval-shikimate-3-phosphate synthase for Equivalence Studies. MSL-12574	438076-03	Monsanto Compar	y OWN	lnert Ingredient
<u>N/A</u>	Monsanto Company (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Animals Data in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPS. Transmittal of 4 studies.	436433-00	Monsanto Conigar	y DWN	tnert Ingredient
885.1 t00	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. Padgene (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30/14: 12901	436433-01	Monsanto Compa		lnert Ingsedient
ignature	m-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submil only Paper version.

⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street S.W. Washington, DC 20460. Do not send the form to this address.

	DA DA	TA MATRIX			
ate: December 17, 2009			EPA Re	g, No./File Symbol: 524-551	Page 45 of 5
	Lindbergh Blvd., St. Louis, MO 63167			MON 88017	
gredient B.J. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) necessary	for its production in	event MON 88017 com (OECD	Unique Identifier: MON-880	7-3)
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.t100	Lee, T., M. Baitey, C. Smith, J. Zeng, E. Elswick and P Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in Escherichia coli and European Com Borer Resistant Com. Lab Project Number: 94-01-39-10: MSL-13920	436433-02	Monsanto Company	OWN	Inert Ingredient
885.3050	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223	436433-03	Monsanto Company	OWN	inert ingredient
885.1100	Ream, I., M. Bailey, I. Leach and S. Padgette (1993). Assessment of the in vitro Digestive Fale of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949	436433-04	Monsanto Company	OWN	tnert Ingredient
N/A_	Revisions and Clarification to the Terms & Conditions of Registration for Corn Event MON 863 and YieldGard® Plus Corn; Progress Report on Multiple IRM-Related Activities for MON 863; and Response to EPA Letter Dated August 13, 2004. Submitted 7/1/2005.	N/A	Monsanto Company	OWN	Terms & Conditions
N/A	Siegfried, B. and T. Spencer (2005). Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 Toxin from Bacillus thuringinesis. This report satisfies the Insect Monitoring Terms & Conditions.	467259-01	Monsanto Company	OWN	Terms & Conditions
Signature	un	222 226 22 446	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35/9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	TA MATRIX			,
Date: December 17, 2009			EP	A Reg. No./File Symbol: 68467-5	Page 46 of 57
Applicant's/Registrant's Name				222 422	
	N. Lindbergh Blvd., St. Louis, MO 63167	5 %		oduct: Herculex® RW Insect Pro	
ngredient B.t. Cry34/35Al Suideline Reference Number					,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Suideline Releience Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Phosphinothricin acetyltransferase (PAT) protein: In Vitto Digestibility Study	45041501	64867	PER	
	PS149B1 Binary Insecticidal Crystal Protein: Acute Toxicity to the Earthworm in an Artificial Substrate	45360201	68467	PER	
	Microbial PS149Bt Binary Delta-Endotoxin: Maize- Insect-Pest Susceptibility Study	45242204	68467	PER	
	Comparison of the Amino Acid Sequence of the Bacillus thuringiensis Strain PS149B1 13.6 kDa and 43.8 kDa Insecticidal Crystal Proteins to Known Protein Allergens	45242205	68467	PER	
	PS149B1 14 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242207	68467	PER	
	PS149B1 44 KDA Protein: Acute Oral Toxicity Study in CD-1 Mice	45242208	68467		
Signature	en		Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Manag	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Monsanto Company

07-CR-192E-2

Page 65 of 175

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D	ATA MATRIX			
Date: December 17, 2009			E	PA Reg. No./File Symbol: 68467-5	Page 47 of 57
Applicant's/Registrant's Name & Monsanto Company, 800 N	& Address: Lindbergh B)vd., St. Louis, MO 63167		Pi	roduct: Herculex® RW Insect P	rotection
Ingredienl B.I. Cry34/35Ab	1 Insecticidal Crystal protein and the genetic material ne	cessary for its produ	ction (plasmid insert PHP17	662) in corn (OECD Identifier; DAS	-59122-7)
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Status	Note
	PS149Bt t4 KDA and 44 KDA Proteins: Acute Oral Toxicity study in CD-t Mice	45242209	68467	PER	
	PS t49B Binary Insecticidal Crystal Protein: A Dictary Toxicity Study with the Ladybird Beetle	45242210	68467	PER	
	The Tri-Trophic Interaction Between P8 t49Bt Transformed Maize, Corn Leaf Aphid and Ladybird Beetle	45242211	68467	PER	
	In Vitro Digestibility of PS149B1 Proteins	45242212	68467	PER	
	Microbial PS t49B t Binary Insecticidal Crystal Protein, Pollen Expressing PS t49B t Binary Insecticidal Crystal Protein, and Individual PS t49B t t4kDa and 44 kDa Insecticidat Crystal Proteins: Evaluation of Dietary Exposure on Honeybee Development	45340701	68467	PER	***************************************
Signature A. a	onic and Paper versions available. Submit only Paper ver		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana		nal Use Copy

EPA Form 8510-85 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

Form Approved OMS No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address,

	D/	ATA MATRIX			
Date: December 17, 2009				EPA Reg. No./File Symbol: 68467-5	Page 48 of 57
	Lindbergh Blvd., St. Louis, MO 63167		Product: Herculex® RW Insect I		
Ingredient B.r. Cry34/35Ab	I Insecticidal Crystal protein and the genetic material ne	cessary for its produ	ection (plasmid insert PHP	17662) in com (OECD Identifier: DA	S-59122-7)
Guideline Reference Number	Guldeline Sludy Name	MRID Number	Submitter	Status	Note
	Thermolability of PS149B Binary Della-Endotoxin	45358401	68467	PER	
	Heat Lability of Individual Proteins of the PS149B1 Binary ICP	45584501	68467	PER	
	In Vitro Simulated Gastric Fluid Digestibility Study of Microbially Derived Cry34Abt Protein	45584502	68467	PER	
	Assessment of Chronic Toxicity of Diet Containing Bacillus thuringiensis PS149B1 Insecticidal Crystal Protein to Collembola (Folsomia candida)	45790406	68467	PER	
	Characterization of Cry34Abt and Cry35Abt from Recombinant Pseudomonas Fluorescence and Transgenic Maize	4579040	68467	PER	
Signature A. CV	n		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mar	Date December 17, 2009	

EPA Form 8578-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public teporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the butden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	ATA MATRIX			
Date: December 17, 2009				PA Reg. No./File Symbol: 68467-5	Page 49 of 57
	. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect P	
Ingredient B.t. Cry34/35Ab	1 Insecticidal Crystal protein and the genetic material ne	cessary for its produ	uction (plasmid insert PHP1	7662) in corn (OECD Identifier, DAS	5-59122-7)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PS t49B t Binary Insecticidal Crystal Protein: An 8-Day Dietary Study with the Rainbow Trout, Oncorhynchus mykiss, Walbaum	45790403	68467	PER	
	PS149Bt Binary Insecticidat Crystat Protein: An Acute Toxicity Study with the Daphnid, Daphnia magna Straus	45790404	68467	PER	
	PS 149B1 Binary Insecticidal Crystal Protein: Dietary Toxicity to Parasitic Hymenoptera (Nasonia vitripennis)	45790405	68467	PER	
	PS 149B1 Insecticidal Crystat Protein: Dictary Toxicity to Green Lacewing Larvae (Cltrysoperta camea)	45790407	68467	PER	
	SDS-PAGE Sensitivity Analysis for Cry35Abt in Support of the Simulated Gastric Fluid Digestion Study MRID#45242212	45790408	68467	PER	
Signature 4- a	N-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address,

	DA	ATA MATRIX			
Date: December 17, 2009				EPA Reg. No./File Symbol: 68467-5	Page 50 of 5
Applicant's/Registrant's Name 8 Monsanto Company, 800 N	Address: Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Pr	otection
Ingredient B.t. Cry34/35Ab	I Insecticidal Crystal protein and the genetic material ne	cessary for its produ	ection (plasmid insert PHP	17662) in corn (OECD Identifier: DAS	-59122-7)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Trait Durability and Experimental Use of Transgenic Maize Expressing the Insecticidal Crystalline Proteins Cry34Abl and Cry35Abl	45790409	68467	PER	
	Degradation of Microbial Binary PS149B1 Delta- Endotoxin in a Representative Soil from the Mid-Western USA Maize-Growing Region	45242214	68467	PER	
	Characterization of DNA Inserted into Transgenic Com Events E4497.42 1.34, E4497.45.2.16, E4497.59.1.10, E4497.66.1.27, E4497.71.1.29 and E4497.71.1.33	45790402	68467	PER	
	Field Efficacy of Cry34Ab1/Cry35Ab1 Maize Events Against Corn Rootworms	45790410	68467	PER	
	Summary of Heat Lability Studies with Cry34Ab1/Cry35Abt	4580360t	68467	PER	
Signature J. av	2—		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	Date December 17, 2009	

EPA Forth 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for Ihls collection of information is estimated to average 0.25 hours per response for registration activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 f M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D/	TA MATRIX			
Date: December 17, 2009			E	PA Reg. No./File Symbol; 68467-5	Page St of S
	. Lindbergh Blvd., St. Louis, MO 63167			roduct Herculex® RW Insect Pr	
Ingredient B.t. Cry34/35Ab	I Insecticidal Crystal protein and the genetic material nec	essary for its produ	iction (plasmid insert PHP t7	662) in corn (OECD Identifier: DAS	-59122-7)
Guldeline Reference Number	Guideline Sludy Name	MRID Number	Submitter	Status	Note
	Slide Presentation Summarizing Cry34Ab1/Cry35Ab1 Heat Inactivation Studies.	458602 <u>0</u> 1	68467	PER	
	Independent Laboratory Validation Pioneer Hi-Bred International, Inc. ELISA Method for the Quantitification of Cry34Ab1Protein from Transgenic Plants	4612390 t	68467	PER	
	Independent Laboratory Validation of Dow AgroSciences Method GRM 03.13, "Determination of Cry35Ab1 Insecticidal Crystal Protein in Maize Tissue by enzime Linked Immunosorbent Assy"	461239 <u>02</u>	68467	PER	
	Cry34/35 Protein Distribution and Familiarity	46123903	68467	PER	
	Agronomic Characteristics, Quantitative ELtS A and Nutrient Composition Analysis of Hybrid Maize Lines Containing Cry34Ab1, Cry35Ab1 and PAT Genes: Chile Locations	46123904	68467	PER	8
Signature . M			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date Deccmber 17, 2009 ger	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

€EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per tesponse for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency,

	D/	ATA MATRIX			
Date: December 17, 2009			EP.	A Reg. No./Fite Symbol: 68467-5	Page 52 of 53
Applicant's /Registrant's Name & Monsanto Company, 8 0 0 N	Address; Lindbergh Blvd., St. Louis, MO 63167		Pro	oduct: Herculex® RW Insect Pro	otection
Ingredient B.t. Cry34/35Ab	I Insecticidal Crystal protein and the genetic material ne	cessary for its produ	ection (plasmid insert PHP176	662) in com (OECD Identifier: DAS-	59122-7)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Biological equivalency of Cry34/35Abl insecticidal crystal protein in transgenic plants and derived from transgenic Pseudomonas florescens	46123905	68467	PER	
	Characterization of Cry34Ab1 and Cry35Ab1 Proteins Derived from Transgenic Majze event E4497.59.1.22 (DAS-59122-7)	46123906	68467	PER	
	Characterization of Phosophinothricin Acelytransferase (PAT) Derived from Transgenic Maize Event E4497.59, t,22	46123907	68467	PER	
	Characterization of DNA Inserted into Transgenic Corn Events DAS45216-6 and DAS-59122-7	46123908	68467	PER	
	Detailed characterization of DNA inserted into transgenic corn events DAS-45216-6 and DAS-59122-7	46123909	68467	PER	
Signature	ur-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manag	Date December 17, 2009	

07-CR-192E-2

Form Approved OMB No. 2070-0060

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paporwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 f37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D	ATA MATRIX			
Date: December I7, 2009 Applicant's/Registrant's Name 8	Addrage		EI	PA Reg. No./File Symbol: 68467-5	Page 53 of 57
	Lindbergh Blvd., St. Louis, MO 63167		Pr	oduct: Herculex® RW Insect P	rotection
Ingredient B.t. Cry34/35Ab	1 Insecticidal Crystal protein and the genetic material ne	cessary for its produ	uction (plasmid insert PHP17	662) in corn (OECD Identificr: DAS	3-59122-7)
Guldeline Reference Number	Guideline Sludy Name	MRID Number	Submilter	Status	Note
	Evaluation of microbe derived cry34Ab1 and Cry35Ab1 proteins for protein synthesis inhibitation activity	46123910	68467	PER	
	Nutritional Equivalency Study of Maize Containing Cry34Ab1 and Cry35AB1. Poultry Feeding Study	46123911	68467	PER	
	The effect of Cry34Abt/Cry35Ab1 proteins on the development and mortality of the Ladybird beetle Colemegilla maculata DeGeer	46123912	68467	PER	
	Non-Jarget Invertebrate Ecological Risk Assessment for Field Com Expressing Cry34Ab1 and cry35Ab1 Insecticidal Crystal Proteins in Event DAS-591227	46123913	68467	PER	
	Evaluation of the impact of com rootworm control strategies on non-target arthropods	46123914	68467	PER	
Signature La	Manage was long muliable Submit only Paper 100		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date December 17, 2009	

EPA Form 8670-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

€EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Roduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the Instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the torm to this address. DATA MATRIV

		ATA MATRIX			
Date: December 17, 2009			1	EPA Reg. No./File Symbol: 68467-5	Page 54 of 5
	Lindberglt Blvd., St. Louis, MO 63167		Product: Herculex® RW Insect Pi		
ngredlent B.t. Cry34/35Ab	I Insecticidal Crystal protein and the genetic material ne	cessary for its produ	action (plasmid insert PHP1	7662) in corn (OECD Identifier: DAS	-59122-7)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
AVII.	Investigations into Dose of Cry34Ab1/Cry35Ab1 Rootworm-Resistant Maize Event DAS-59122-7 Against Western and northern Corn Rootworms in Support of Trait DurabilityPlans	46123915	68467	PER	
, 100 , 100	Effect on Western Corn Rootworm Adults of Feeding on Cry34/35Abl-Corn Rootworm Protected Corn Tissue and Implications for Product Durability	46123916	68467	PER	
	Evaluation of endangered/Illreatened insect species relative to the use of Cry34Ab/Cry35Ab1 com rootworm- resistant maize hybirds	46123917	68467	PER	
	Trait Durability Plan for Cry34/35-Corn Rootworm Protected corn Event DAS-59122-7 Following Commercialization	46123918	68467	PER	
	Simulations of Corn Rootworm Adaptation to Cry34/35- Com Rootworm Protected Corn in Support of Trait Durability Plans for Event DAS-59122-7	46123919	68467	PER	
Signature of an	-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Man	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other as pect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: December 17, 2009			E	PA Reg. No./File Symbol; 68467-5	Page 55 of 5
	Lindbergh Blvd., St. Louis, MO 63167			roduct: Herculex® RW Insect Pr	
Ingredient B.t. Cry34/35Ab	I Insecticidal Crystal protein and the genetic material net				12/30/
Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter	Status	Note
	Digestion of Allergenic and Non-Allergenic Proteins in Simulated Gastric Fluid	46123920	68467	PER	
	Public Interest Document for Cry34/35Ab1 Corn Rootworm-Protected Corn	46123921	68467	PER	
	Evaluation of the Sequence Similarities of the Cry34Ab1, ery35Ab1, and PAT Proteins to the Public Protein Sequence Datasets	46584701	68467	PER	
	OECD. t9. Consensus document of general information concerning the genes and their enzymes that confer tolerance to phosphinothricin herbicide. ENV/JM/MONO(99)13.26p.		68467	PL	
	Safety evaluation of the phosphinothricin acetyltransferase proteins encoded by the pat and bar sequences that confer tolerance to glufosinate-ammonium herbicide in transgenie plants. Regulatory Toxicology & Pharmacology 41 (2005) 134-149.		68467	PL	
Signature of Con-			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana	Date December 17, 2009	

EPA Form 8570-85 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Roduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 f37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D	ATA MATRIX			
Date: December 17, 2009		2 2 200	E	EPA Reg. No./File Symbol: 68467-5	Page 56 of 5
	. Lindbergh Blvd., St. Louis, MO 63167			Product: Herculex® RW Insect Pr	
Ingredient B.t. Cry34/35Ab	I Insecticidal Crystal protein and the genetic material ne	cessary for its produ	iction (plasmid insert PHP)	7662) in com (OECD Identifier: DAS	-59122-7)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Product Characterization Data for Bacillus thuringiensis Cry34Abt and Cry35Ab1 Proteins Expressed in Transgenie Maize Plants (PHP17662)	4579060 t	68467	PER	
	Quantitative ELISA Analysis of Cry34Ab1 and Cry35Abt Proteins Expressed in Maize Plants Transformed with the Vector PHP17662	4 <u>5</u> 833201	68467	PER	
	Addendum to MRID # 45790601. Product Characterization Data for Bacillus thuringiensis Cry34Abt and Cry35Abt Proteins Expressed in Transgenic Maize Plants (PHP17662)	4603000 t	68467	PER	
	Probe MOA Studies to Assess Potential for Protein Synthesis Inhibition by Bacillus thuringiensis PS 149B1 cry34Ab1/cry35Ab1 Proteins in a Rabbit Reticulocyte Assay: Re-examination of Lab Notebook Data	45942801	68467	PER	
	Digestion efficiency of allergens and non-allergens in simulated gastric fluid	46388601	68467	PER	
Signature J_ a	onic and Paner versions available. Submit only Paner ver		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana		nal Use Conv

EPA Form 8570-25 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	Ŋ.	ATA MATRIX			
Date: December 17, 2009			E	PA Reg. No./File Symbol: 68467-5	Page 57 of 57
Applicant's/Registrant's Name 8 Monsanto Company, 800 N	. Lindbergh Blvd., St. Louis, MO 63167			roduct: Herculex® RW Insect P	
Ingredient B.t. Cry34/35Ab	1 Insecticidal Crystal protein and the genetic material ne	cessary for its produ	ction (plasmid insert PHP17	662) in corn (OECD Identifier: DAS	S-59122-7)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Evaluation of the Sequence Similarities of the Cry34Ab1, Cry35Ab1, and PAT Proteins to the Public Protein Sequence Datasets	4658470 t	68467	PER	
——————————————————————————————————————	Investigation of Potential Interaction between Cry1F and the Binary Cry34Ab1/Cry35Ab1 Proteins	46343806	68467	PER	
	onic and Paper versions available. Submit only Paper vers		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mana		rnal Use Copy

EPA Form 8578/35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director OPPE Information Management Division (2137). U.S. Environmental Protection Agency

		DATA MATRIX			
Date: December 17, 2009			EPA Reg.	No./File Symbol; 524-58	B1 Page Lof 5
Applicant's/Registrant's Name &	Address: Lindbergh Blvd., St. Louis, MO 63	167		Product: MON 89034 × MON 88017 × DAS-	*TC1507 ×
ngredient Bacillus thuringier	ssis Cry1A.105, Cry2Ab2, Cry1F, Cry3E Production in MON 89034 × TC1507 ×	3b1, Cry34/35Ab1 Proteins and the Ge	netic Materials (Vectors PV-ZMI Unique Identifier: MON-89Ø34-	R245, PHP8999, PV-ZN	AIR39, and
Suideline Reference Number	Guideline Sludy Name	MRID Number	Submitter	Status	Note
			Monsauto Сощрапу	OWN	Administrative This Applicatio
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	Benefits This Application
Signature /	n		Name and Title	Date	

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

AND AND THE WAY AND TO THE		Washington, D.C	. 20460	STORY OF SECT 12 SERVICES OF STORY	25-31 (5 - 1964) - 25 - 27 - 27
response for reregistration and other aspect of this collection o	tice: The public reporting burden for this collecti special review activities, including time for readi f information, including suggestions for reducing n, DC 20460. Do not send the form to this addre	ng the instructions and completing the burden to: Director, OPPE Info	the necessary forms. Send co	mments regarding the bur	den estimate or any
		DATA MATRIX			
Date: December 17, 2009			EPA Re	g. No,/File Symbol: 524->	(XX Page 2 of 57
Applicant's/Registrant's Name 8	Address: Lindbergh Blvd., St. Louis, MO 63167			ct: MON 89034 × TC15 DAS-59122-	07 × MON 88017 ×
ngredient Bacillus thuringte	nsis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, C r Production in MON 89034 × TC1507 × MON				
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Status	Note
			Monsanto Company Monsanto Company	OWN	Administrative Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsarto Company	OWN	Product Characterization
Signature A. a	m) J.	lame and Title . Austin Burns, Ph.D. legulatory Affairs Manager	Date December 17, 200	09

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paporwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX Date: December 17, 2009 EPA Reg. No./File Symbol: 524-XXX Page 3 of 57 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7 × MON-88Ø17-3× DAS-

PHP 17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507 × MON-88017-3 × DAS-59122-7)

Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Stalus | Note

Guideline Reference Number	Guideline Study Name	MRIO Number	Submilter	Stalus	Note
			Monsanto Company	OWN	Product Characterization
		,	Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Enviroumental Assessment
Signature A. Cl	n-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form 8979-45 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0,25 hours per response for registration activities and 0,25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency. 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address. DATA MATRIX Date: December 17, 2009 EPA Reg. No./File Symbol: 524-XXX Page 4 of 57 Applicant'sfRegIstrant's Name & Address: Product: MON 89034 × TC1507 × MON 88017 × Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 DAS-59122-7 Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) Necessary for their Production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (OECD Unique Identifier: MON-89034-3 × DAS-01507 × MON-88017-3 × DAS-01507 × MON-8017-3 × M 59122-7) Guideline Reference Number Guideline Sludy Name MRID Number Submitter Status Note Environmental Assessment OWN Monsanto Company Environmental Assessment Monsanio Company OWN IRM Monsanto Company OWN Environmental Assessment Monsanto Company OWN Environmental Assessment Monsanto Company OWN Date Signature Name and Title December 17, 2009 J. Austin Burns, Ph.D. Regulatory Affairs Manager

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	<u> </u>	DATA MATRIX			
late: December 17, 2009	7079 82846 82977 C 07479 10 5798	200 March (1990) 12 (1990) 14 (1990) 15 (1990)	EPA Reg.	No./Fite Symbot: 524-575	Page 5 of 5
pplicant's/Registrant's Name &					N 20
Ionsanto Company, 800 N.	Lindbergh Blvd., St. Louis, MO 6316	67		MON 89034	
ngredient Bacillus Ihuring dentifier: MON-89034-3)	iensis Cry1A.105 and Cry2Ab2 Proteins a	nd the Genetic Material (Vector PV-ZA	AIK245) Necessary for their Pi	oduction in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Administrative
				}	
				(Product
		·	Monsanto Company	OWN	Characterization
					Product
		. 1	Monsanto Company	OWN	Characterization
		¹⁴ ax		}	
					Product
		T. Carlotte and Car	Monsanto Company	OWN	Characterization
			Monsanto Company	OWN	Product Charocterization
Signature	24 and 24 and	N	ame and Title	Date	
1.00	1		Austin Burns, Ph.D.	December 17, 2009	

(EBX Form 8570-35 (9-97) Etectronic and Paper versions available, Submit only Paper version.

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA Re	g, No./File Symbol: 524-575	Page 6 of 57
	Lindbergh Blvd., St. Louis, MO 63167			MON 89034	
ngredlent Bacillus thuring (dentifier: MON-89034-3)	ensis CrylA.105 and Cry2Ab2 Proteins and	d the Genetic Material (Vector PV-	ZMIR245) Necessary for their I	roduction in MON 89034 (OF	CD Unique
Guideline Reference Number	Guidetine Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	own	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
Signature Law	1	1	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

(EPA Form 8570-35 (9-97) Etectronic and Paper versions available. Submit only Paper version.

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009	20 1950 AND 1084 MANN AND		EPA Reg	. No./File Symbol: 524-575	Page 7 of 57
Applicant's/Registrant's Name &		_			
	Lindbergh Blvd., St. Louis, MO 6316			MON 89034	OD W
Ingredient Bacillus rhuring. Identifier: MON-89Ø34-3)	iansis Cry1A.105 and Cry2Ab2 Proteins an	d the Genetic Material (Vector PV	-ZMIR245) Necessary for their P	roduction in MON 89034 (Of	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitler	Status	Nole
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Human Health Assessment
		.⇔. 1 •	Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	own	Human Health Assessment
Signature	en-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Roduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per

		DATA MATRIX			
Dale: December 17, 2009			EPA R	eg. No./File Symbol: 524-575	Page 8 of 57
Applicant's/Registrant's Name & Address Monsanto Company, 800 N. Lindbe		167	Produc	t: MON 89034	
		s and the Genetic Material (Vector PV-	ZMIR245) Necessary for their	Production in MON 89034 (OF	CD Unique
	ine Study Name	MRID Number	Submitter	Status	Nole
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
		, , , , , , , , , , , , , , , , , , ,	Monsanto Company	OWN	Human Health Assessment
		e j	Monsanto Company	DWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
		a La escarión de en la escarión de escentia	Monsanto Company	рум	Fluman Health Assessment
Signature Lann		1	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		D	ATA MATRIX			
Date: December 17, 2009				EPA Reg.	No./File Symbol: 524-575	Page 9 of 57
Applicant's/Registrant's Name &						
	. Lindbergh Blvd., St. Louis, MO 631				MON 89034	
ngredlent Bacillus thuring Identifier: MON-89Ø34-3)	riensis Cry (A.105 and Cry2Ab2 Proteins a	and the Geneti	c Materiał (Vcctor PV-	ZMIR245) Necessary for their Pr	oduction in MON 89034 (OF	CD Unique
Guideline Reference Number	Guideline Study Name		MRID Number	Submitter	Status	Note
				Monsanto Company	OWN	Human Health Assessment
			. <u> </u>	Monsanto Company	OWN	Human Health Assessment
			Á	Monsanto Company	OWN	Environmental Assessment
				Monsanto Company	OWN	Environmental Assessment
		A 844 36		Молsanto Company	OWN	Environmental Assessment
Signature Law	u		*	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA/Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕ EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Date: December 17, 2009			EPA Reg.	No./File Symbot: 524-575	Page t0 of 57
Applicant's/Registrant's Name & Monsanto Company, 80 0 N.	Address: Lindbergh Blvd., St. Louis, MO 63167	į	Product:	MON 89034	
ngredient Bacillus thuring Identifier: MON-89034-3)	fensis Cry IA. 105 and Cry2Ab2 Proteins and	the Genetic Material (Vector PV-	ZMIR245) Necessary for their Pr	oduction in MON 89034 (OI	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
		* <u></u>	Monsanto Company	OWN	Environmental Assessment
		e di ta di	Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmentat Assessment
Signature Ov	u-	1	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

		DATA MATRIX			-,
Date: December 17, 2009			EPA Rec	J. No./File Symbol: 524-575	Page tt of 5
Applicant's/Registrant's Name					
	I. Lindbergh Blvd., St. Louis, MO 6316 iensis Cry1A.105 and Cry2Ab2 Proteins an			MON 89034	N. I. Laura
dentifier: MON-89Ø34-3)	iensis CiyiA.103 and CiyzAb2 Flotenis an	to the Genetic Material (vector F v-ZM	MRZ43) Necessary for their Fi	onnetion in MOM 93034 (OEc	n Duidne
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Euvironmental
		·	Monsanto Company	OWN	Assessment
		(Sp.)-		1	
				Olypy	Environmental
			Monsanto Company	OWN	Assessment
				-	
					Environmental
		ý.	Monsanto Company	OWN	Assessment
					Environmental
			Monsanto Company	OWN	Assessment

		147			## 0 E
			Monsanto Company	OWN	Environmental Assessment
Signature /	n-	21	lame and Title	Date	220
	11	1.1.	Austin Burns, Ph.D.	December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA Reg	, No./File Symbol: 524-575	Page 12 of 57
	. Lindbergh Blvd., St. Louis, MO 631		Product:	MON 89034	
ngredient Bacillus thuring dentifier: MON-89034-3)	riensi's Cry IA. 105 and Cry2Ab2 Proteins	and the Genetic Material (Vector PV-2	ZMIR245) Necessary for their P	roduction in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submilter	Slatus	Nole
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
		, a	Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature A. A.	n	\.	Name and Title J. Austin Bums, Ph.D. Regutatory Affairs Manager	Date December 17, 2009	

07-CR-192E-2

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0,25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009		Name	EPA Reg. I	No./File Symbol: 524-575	Page 13 of 57
	Lindbergh Blvd., St. Louis, MO 6316;			MON 89034	· · · · · · · · · · · · · · · · · · ·
Ingredient Bacillus thuring Idenlifier: MON-89Ø34-3)	iensis Cry I A.105 and Cry2Ab2 Proteins an	d the Genetic Matchai (vector P v-Z	MIK245) Necessary for their Pro	duction in MON 89034 (Of	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Stalus	Noie
		\$ 	Monsanto Conipany	OWN	Environmental Assessment
			Monsanio Company	OWN	Environniental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature 1. A	n-	\ <u> </u>	Jame and Title . Ausiin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Ingredient Bacillus Huningiensis Cry IA.105 and Cry2Ab2 Proteins and the Genetic Material (Voctor PV-ZMIR245) Necessary for their Product Identifier: MON-89034-3) Guideline Reference Number Guideline Study Name MRID Number Submitter Monsanto Company Monsanto Company Monsanto Company Monsanto Company Signature Name and Title J. Austin Burns, Ph.D.		
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Ingredient Bacillus Inturnigiensis Cry IA.105 and Cry2Ab2 Proteins and the Genetic Material (Voctor PV-ZMIR245) Necessary for their Product Identifier: MON-89/034-3) Guideline Reference Number Guideline Study Name MRID Number Submitter Monsanto Company Monsanto Company Monsanto Company Signature Name and Title J. Austin Burns, Ph.D. J. Austin Burns, Ph.D.	/File Symbot 524-575	Page t4 of 5
Identifier: MON-89@34-3) Guideline Reference Number Guideline Study Name MRID Number Submitter		
Monsanto Company Monsanto Company Monsanto Company Monsanto Company Name and Title J. Austin Burns, Ph.D.	ction in MON 89034 (OE	3CD Unique
Monsanto Company Monsanto Company Monsanto Company Monsanto Company Name and Title J. Austin Burns, Ph.D.	Stalus	Note
Monsanto Company Monsanto Company Monsanto Company Name and Title J. Austin Burns, Ph.D.	OWN	tRM
Monsanto Company Monsanto Company Name and Title J. Austin Burns, Ph.D.	OWN	Benefits
Signature Monsanto Company Name and Title I J. Austin Burns, Ph.D. I	OWN	Mísc.
Signature Name and Title J. Austin Burns, Ph.D.	OWN	Misc.
J. Austin Burns, Ph.D.	own	Misc.
Regulatory Affairs Manager	Dale December 17, 2009	

Form Approved OMB No. 2070-0060

Monsanto Company

07-CR-192E-2

Page 90 of 175

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	DATA MATRIX			
Date: December 17, 2009		EPA Reg.	. No./File Symbol: 68467-2	Page 15 of 57
Applicant's/Registrant's Name & Address:				1885 N 1885
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product:	Herculex® I Insect Protect	ction
ingredient B.t. Cry1F protein and the genetic material necessary for production	(plasmid insert PHP8999)	in maize (OECD Identifier. DA	AS-Ø15Ø7-1)	
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
		68467	PER	<u>-</u>
	**************************************	68467	PER	
		68467	PER	
		68467	PER	
		68467	PER	
Signature & and an analysis of the signature	J.	lame and Title Austin Burns, Ph.D. egulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response tor registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the torm to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA Reg.	. No,/File Symbol: 68467-2	Page 16 of 57
Applicant's/Registrant's Name Monsanto Company, 800 N	N. Lindbergh Blvd., St. Louis, MO 6316		Product:	Herculex®1 Insect Prote	
	tein and the genetic material necessary for pr	1.00			
Guideline Reference Number	Guideline Sludy Name	MRID Number	<u>Submitter</u>	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
		_	68467	PER	
¥ 10 200 1 200 1			68467	PER	
Signature LA	V	J. 	ame and Title Austin Burns, Ph.D. gulatory Affairs Manager	Date December 17, 2009	

EPA Form 8579-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

DATA MATRIX

	·	DATA MATRIX			
Date: December 17, 2009			EPA R	eg. No,/Fite Symbol: 68467-2	Page 17 of 57
Applicant's/Registrant's Name &	& Address: I. Lindbergh Blvd., St. Louis, MO 63167		Produc	et: Herculex® I Insect Prote	
	in and the genetic material necessary for produ	ction (plasmid insert PHP8999)			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		_	68467	PER	
		4			
		_	68467	PER	
		*	68467	PER	
			68467	PER	
			2045		
		Kirk	68467	PER	100 TO 100 T
			68467	PËR	
Signature A CM		J	lame and Title Austin Bums, Ph.D. Legulatory Affairs Manager	Date December 17, 2009	

EPA Forth 8870-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

DA`	TA MATRIX			
Date: December 17, 2009		EPA Reg.	No.tFile Symbol; 68467-2	Page 18 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product:	Herculex® I Insect Protect	ction
Ingledient B.t. Cry1F protein and the genetic material necessary for production (plas	mid insert PHP8999) in 1	naize (OECD Identifier: DA	S- Ø15Ø7-I)	
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Slatus	Note
		68467	PER	
		68467	PER	
	· · · · · · · · · · · · · · · · · · ·	68467	PER	
		68467	PER	
		68467	PER	
Signature Signature AV Signature Signatu	J. At Regi	e and Title stin Bums, Ph.D. latory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Form Approved OMB No. 2070-0060

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for fills collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIV

		DATA MATRIX			
Date: December 17, 2009			EPA Re	g. No.fFile Symbot: 68467-2	Page 19 of 57
Applicant's/Registrant's Name &	k Address: . Lindbergh Blvd., St. Louis, MO 6316	7	Product	2000 N WARREN SARK IN	<u> </u>
	in and the genetic material necessary for pr			T	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			68467	PER	·
			68467	PER	
			68467	PER	
			68467	PER	
		aga aya ay ta ay a shekka	68467	PER	
	n-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	
DA Form 0870 26 /0 07) Electr	onic and Daner versions available. Submit or	the Danne wareign		Public File Co	CPATE .

EPA Form 8\$70-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

€EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for teregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	DATA MATRIX			
Date: December 17, 2009		EPA Reg	. No./File Symbol: 68467-2	Page 20 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 6		Product:	Herculex® I Insect Prote	
Ingredient B.r. Cry1F protein and the genetic material necessary for	or production (plasmid insert PHP8999) in	maize (OECD Identifier: DA	AS- Øt5Ø7-1)	
Guideline Reference Number Guideline Study Name	MRID Number	Submitler	Status	Note
		68467	PER	
Signature J. an	J. A	ne and Title ustin Burns, Ph.D. ulatory Affairs Manager	Date December 17, 2009	201 20 5000 5

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to; Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX			
	EPA Reg	. No./File Symbol: 68467-2	Page 21 of 57
	Product:	Herculex® I Insect Prote	
	maize (OECD Identifier, Da	AS- Øl 5Ø7-1)	
MRID Number	Submitter	Status	Note
	68467	PER	
J. / Re	Austin Burns, Ph.D.	December 17, 2009	- 20
	duction (plasmid insert PHP8999) in MRID Number Na J. A	EPA Reg Product: duction (plasmid insert PHP8999) in maize (OECD Identifier: Da MRID Number Submitter 68467 68467 68467 Name and Tille J. Austin Burns, Ph.D. Regulatory Affairs Manager	EPA Reg. No./File Symbol: 68467-2 Product: Herculex® I Insect Protectuction (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-1) MRID Number Submitter Status 68467 PER 68467 PER 68467 PER 68467 PER Name and Tille J. Austin Burns, Ph.D. Regulatory Affairs Manager

EPA Form 8576-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MATRIX			7
Date: December 17, 2009		EPA Reg	. No./File Symbol: 68467-2	Page 22 of 53
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product:		ction
ngredient B.r. CryIF protein and the genetic material necessary for proc	duction (plasmid insert PHP8999) i	n maize (OECD Identifier: DA	AS- Ø15Ø7-1)	
Guideline Reference Number Guideline Study Name	MRID Number	Submilter	Status	Note
		68467	PER	
Signature Lan	J.	fame and Title Austin Burns, Ph.D. egulatory Affairs Manager	Date December 17, 2009	

EPA Form(8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

⊕ EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA R	eg. No.4File Symbot: 68467-2	Page 23 of 57
Applicant's/Registrant's Name 8		1.7			· · · · · · · · · · · · · · · · · · ·
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Lindbergh Blvd., St. Louis, MO 63		Produc		ction
		production (plasmid insert PHP8999) i			21.6
Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter	Status	Note
				1	
		1	2012	W. 175	
		*	68467	PER	
			68467	PER	
			00407	TER	
		i de la companya de		Î	
			68467	PER	
		<u>.</u>	68467	PER	
				1	
			68467	PER	
Signature / A	n-	J.	ame and Title Austin Burns, Ph.D. egulatory Affairs Manager	Date December 17, 2009	(200 3:0000 ES
DA C 0570/00 40 070 Flade	and the second plants of the s		Sara-Al Viscolo Manuel	Dublic File O	

EPA Form 8529-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Nottco: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MATRIX			
Date: December 17, 2009		EPA Re	g. No./File Symbot: 68467-2	Page 24 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Herculex® I Insect Prote	A 8 4
ngredient B.t. Cry IF protein and the genetic material necessary for	production (plasmid insert PHP8999) in	maize (OECD Identifier: D	AS-Ø15Ø7-1)	
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
		68467	PER	
	and the second s	68467	PER	
A an	J	ime and Title Austin Burns, Ph.D. gulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Fite Copy

Form Approved OMB No. 2070-0060

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX			
	EPA Reg	. No.fFite Symbot: 68467-2	Page 25 of 57
	Product:	Herculex® I Insect Prote	
		7 (A) 10 (A)	
MRID Number	Submitter	Status	Note
	68467	PER	·
	68467	PER	
	68467	PER	
	68467	PER	
	68467	PER	····
J. A	ustin Burns, Ph.D.	Date December 17, 2009	222
	Nai J. A Reg	Product: MRID Number Submitter 68467 68467 Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	EPA Reg. No./Fite Symbot: 68467-2 Product: Herculex® I Insect Protect Ruction (plasmid insert PHP8999) in maize (OECD Identifier: DAS-Ø15Ø7-I) MRID Number Submitter Status 68467 PER 68467 PER 68467 PER 68467 PER Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager

EPA Form 8570-95 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Fllo Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.					
DA1	TA MATRIX				
Date: December 17, 2009			EPA Reg. N	o/File Symbol: 68467-2	Page 26 of 57
Applicant's/Registrant's Name & Address:					2000
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				Ierculex® I <i>Insect Protei</i>	ction
ingredient B.t. CryIF protein and the genetic material necessary for production (plas	mid insert PIIP8999) in maize (OECD Ider	tifier: DAS-	Ø15Ø7-1)	200
Guideline Reference Number Guideline Study Name	MRID Number	Submitter		Status	Note
		68467		PER	
	₹. 	68467		PER	
	* . * .	68467		PER	
		68467	50 200 13 2002-100 16 2001	PER	
		68467		PER	
Signature Lan-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma		Date December 17, 2009	200000 OF SECTION

EPA Form 8870-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and compteting the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Daie: December 17, 2009			EPA R	eg. No,/Fite Symbol; 524-551	Page 27 of 5
Applicant's/Registrant's Name &					<u>-</u>
	Lindbergh Blvd., St. Louis, MO 63167			t: MON 88017	
ngredient B.f. Cry3Bb1 prote	in and the genetic material (vector ZMIR39) neces	sary for its production in en	rent MON 88017 com (OECD	Unique Identifier: MON-88Øt	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
		e ⁱ		,	Product
		* 3	Monsanto Company	OWN	Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
Signature L. Cer		2	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date December 17, 2009	

EPA Form(8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Fito Copy

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W. Washington, DC 20460. Do not send the form to this address.

401 M Street, S.VV., VVasningtor	n, DC 20460. Do not send the form to this add	DATA MATRIX			
Date: December 17, 2009			EPA Reg	No./File Symbol: 524-551	Page 28 of 57
Applicant's/Registrant's Name &		r	D. Link	MONI OPALO	
	Lindbergh Blvd., St. Louis, MO 63167		Product:	MON 88017	
	ein and the genetic naterial (vector ZMIR3)				
Guideline Reference Number	Guideline Sludy Name	MRtD Number	Submitter	Status	Note
		<u> </u>		1	
		e e e e e e e e e e e e e e e e e e e			
				1	Product
		4	Monsanto Company	OWN	Characterization
		<u> </u>			
		g de			
		8		[
					Product
		<u>-</u>	Monsanto Company	OWN	Characterization
		a'		1	
		a de		1	
			Manager Constant	OWN	Product Characterization
		a -	Monsanto Company	OWN	Criaracterization
				1	
		##		i di	
		ž.		- I	Product
			Monsanto Company	OWN	Characterization
		*			
			Maria 12 02	OVAL	Product Characterization
0.	Birthy and Market Washed Speak	<u> </u>	Monsanto Company	OWN Date	Characterization
Signature			Name and Title J. Austin Burns, Ph.D.	December 17, 2009	
-U.Cer	1		Regulatory Affairs Manager	200011001 17, 2007	
FDA F0 0570 25 (0	97) Fiectronic and Paner versions available.		Treatment of the state of the s	P::	oltc Fite Copy

ERA-Form 8570-35 (9-97) Etectronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, 401 M Street, S.W. Washington, DC 20460. Do not send the form to this address

		DATA MATRIX			
Date: December 17, 2009			EPA Reg.	No./File Symbol: 524-551	Page 29 of 57
Applicant's/Registrant's Name &		7		NAME AND ADDRESS OF THE PARTY O	——————————————————————————————————————
	Lindbergh Blvd., St. Louis, MO 63167			MON 88017	
ngredient B.t. Cry3Bb1 prote	ein and the genetic material (vector ZMIR39)	necessary for its production in ev	ent MON 88017 com (OECD Un	ique Identifier: MON-88Ø	7-3)
Guldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
		*	Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
					Product
		*	Monsanto Company Monsanto Company	OWN	Characterization Product Characterization
Signature] 3	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	Committee restrict

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MATRIX			. ,
Date: December 17, 2009		EP	A Reg. No./Fite Symbol: 524-551	Page 30 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			oduci: MON 88017	
Ingredient B.t. Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its production in	event MON 88017 com (OE	CD Unique Identifier: MON-880	17-3)
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
	**************************************	Monsanto Company	OWN	Product Characterization
		Monsanto Company	OWN	Product Characterization
		Monsanto Company	OWN	Human Health Assessment
		Monsanto Company	OWN	Human Mealth Assessment
	ra Line a santini	Monsanio Company	OWN	Human Health Assessment
Signature Law		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Mat	Date December 17, 2009	

EBK Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA UNITED STATES ENVIRONMENTAL PROTECTION AGENCY Form Approved OMB No. 2070-0060

401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

		DATA MATRIX			
ate: December 17, 2009			EPA R	leg. No./File Symbol: 524-551	Page 31 of 5
pplicant's/Registrant's Name & Ionsanto Company, 800 N	. Lindbergh B)vd., St. Louis, MO 63		Produ		
gredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMI	R39) necessary for its production in	event MON 88017 com (OECL	Unique Identifier: MON-88Ø1	7-3)
Suldeline Reference Number	Guideline Study Name	MRID Number	Submitter	Slatus	Note
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	tiuman Itealth Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	оwи	Human Health Assessment
Signature Lav		ANNA ANNA ANA	Name and Title J. Austin Bums, Ph.D. Regulatory Affairs Manage	Date December 17, 2009	

SEPA UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA Reg	. No./File Symbol: 524-551	Page 32 of 5
Applicant's/Registrant's Name & Monsanto Company, 80 0 N	Address: . Lindbergh Blvd., St. Louis, MO 6316	57	Product:	MON 88017	
ngredient B.I. Cry3Bb1 prot	em and the genetic material (vector ZMIR)	39) necessary for its production in eve	ent MON 88017 com (OECD U	nique Identifier. MON-8801	7-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Stalus	Nole
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	own	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature A. Co	·n	Ţ	Name and Title . Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

DAT	A MATRIX			
Date: December 17, 2009		EPA	Reg. No./File Symbot: 524-551	Page 33 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			uct: MON 88017	
Ingredient B.t. Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for				1 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3
Guideline Reference Number Guldeline Study Name	MRID Number	Submitter	Status	Note
		Monsanto Company	OWN	Environmentat Assessment Waived in BRAD
	:	Monsanto Company	DWN	Environmentat Assessment
		Monsanto Company	OWN	Environmentat Assessment Waived in BRAD
		Monsanio Company	own	Environmentat Assessment
		Monsanto Company	own	Environmental Assessment
Signature Signature APA Form 8570-35 (9-97) Etectronic and Paper versions available. Submit only Page		Name and Title I. Austin Burns, Ph.D. Regulatory Affairs Mana		ubtic Fite Copy

NEPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MATRIX				
Date: December 17, 2009			EPA Reg. N	o./File Symbol: 524-551	Page 34 of 57
Applicant's/Registrant's Name & Address;			1		
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				4ON 88017	
Ingredient B.t. Cry3Bb1 protein and the genetic material (vector ZMIR39) necessar		event MON 88017 com	(OECD Uniq	ue Identifier: MON-88Ø1	7-3)
Guideline Reference Number Guideline Study Name	MRID Number	Submitter Submitter		Status	Note
		Monsanto Com	pany	OWN	Environmental Assessment
		Monsanto Com	pany	OWN	Environmental Assessment
		Monsanto Com	pany	OWN	Environmental Assessment
		Monsanto Com	pany	own	Environmentat Assessment
		Monsanto Com	рапу	OWN	Environmental Assessment
Signature EPA Form 8570-35 (9-97) Firectronic and Paner versions available. Submit on		Name and Title J. Austin Burns, Ph.D Regulatory Affairs		Date December 17, 2009	niic File Copy

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

<u> </u>	DATA MATRIX			,
pale: December 17, 2009		EPA Reg.	No./File Symbol: 524-551	Page 35 of 5
pplicani's/Registrant's Name & Address:				- 77-
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MC			MON 88 0 17	
ngredient B.t. Cry3Bb1 protein and the genetic material (vector	ZMIR39) necessary for its production in ever	nt MON 88017 com (OECD Un	ique Idenlifier: MON-88Ø17	7-3)
Suideline Reference Number Guideline Study Name	MRID Number	Submitter	Slatus	Nole
		Monsanto Company	OWN	Environmental Assessment
		Мопѕапіо Сотрапу	OWN	Environmental Assessment
		Monsanio Company	OWN	Environmental Assessment
		Monsanto Company	OWN	Environmental Assessment
		Monsanto Company	own	Environmental Assessment
d-an	J.	ame and Title Auslin Burns, Ph.D egulatory Affairs Manager	Date December 17, 2009	

EPA-Porm 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

		DATA MATRIX			
Date: December 17, 2009			EPA Rec	g. No./File Symbol: 524-551	Page 36 of 51
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			Product:	5 72500 (2250)	
ngredient B.t. Cry3Bb1 prot	ein and the genetic material (vector ZM1R39)	necessary for its production in ev	ent MON 88017 com (OECD L	Inique Identifier: MON-88Ø1	7-3)
Suideline ReIerence Number	Guidetine Study Name	MRID Number	Submitter	Status	Note_
			Monsanto Company	OWN	Environmental Assessment
			Monsanio Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature 1 an	n-		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

ERA form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA UNITED STATES EN

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA Reg.	No./File Symbol: 524-551	Page 37 of 57
Applicant's/Registrant's Name &					
	Lindbergh Blvd., St. Louis, MO 63167		Product:	MON 88017	
Ingredient B.I. Cry3Bb1 prot	ein and the genetic material (vector ZMIR39) n	ecessary for its production in eve	nt MON 88017 com (OECD Un	ique Identifier: MON-88Ø17	7-3)
Guideline Reference Number	Guideline Study Name	MRIÐ Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
	<u> </u>		Monsanto Company	OWN	Environmental Assessment
Signature 1. A	·]]	Name and Title . Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA-Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other a spect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Oivision (2 t37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MATRIX			
Oate: December 17, 2009		EPA Reg	No./File Symbol; 524-551	Page 38 of 57
Applicants/Registrants Name & Address:				
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			MON 88017	
Ingredient B.t. Cry3Bb1 protein and the genetic material (vector ZMIR39) nee	essary for its production in evo	ent MON 88017 com (OECD U	nique Identifier: MON-88Ø1	7-3)
Guideline Relerence Number Guideline Study Name	MRID Number	Submitter	Status	Note
		Monsanto Company	OWN	Environmental Assessment
		Monsanto Company	OWN	Environmental Assessment
		Monsanto Company	own	Environmental Assessment
	di di	Monsanto Company	own	Environmental Assessment
		Monsanto Company	own	Environmental Assessment
		Monsanto Company	OWN	Environniental Assessment
Signature Law	1	Name and Title . Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

07-CR-192E-2

EPA-Porm 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

€ EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W. Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA Reg	, No./File Symbol: 524-551	Page 39 of 5
Applicant's/Registrant's Name & Address:		***			— <u> </u>
Monsanto Company, 800 N. Lindbergh Blvd.,				MON 88017	
ingredient B.I. Cry3Bb1 protein and the genetic n	naterial (vector ZMIR39) necessa	ry for its production in	event MON 88017 com (OECD U	Inique Identifier: MON-88Ø1	7-3)
Guideline Reference Number Guideline Study Na	ame	MRID Number	Submitter	Status	Note
			Monsanto Company	DWN	Environmental Assessment Waived in BRAI
			Monsanto Company	OWN	Environmental Assessment
		1, 12 2, 20 3, 3	Monsanto Company	DWN	Environmental Assessment Granted in BRAI
		3 3 8	Monsanto Company	OWN	Benefits
			Monsanio Company	OWN	Benefits
Signature 1 am			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	Dollarid

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA Reg.	No./Fite Symbol: 524-551	Page 40 of 5
Applicant's/Registrant's Name 8	Address:				
Monsanto Company, 800 N.	Lindbergh Blvd., St. Louis, MO 6316	7	Product:	MON 88017	
ngredlent B.t. Cry3Bb1 prot	ein and the genetic material (vector ZMIR	39) necessary for its production in ev	ent MON 88017 corn (OECD Un	ique Identifier: MON-88Ø17	-3)
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
			Monsanio Company	OWN	Benefits
			Monsanto Company	OWN	Benefits
<u></u>			Monsanto Company	OWN	Benefits/IRM
Signature Law			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Etectronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Oivision (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Oate: December 17, 2009			E	PA Reg. No,/File Symbol; 524-55	Page 41 of 57
Applicant's/Registrant's Name & Address:					
Monsanto Company, 800 N. Lindberg				roduct: MON 88017	
Ingredient B.t. Cry3Bb1 protein and the	genetic material (vector ZMIR39) nece	ssary for its production in o	event MON 88017 com (O	ECD Unique Identifier: MON-88	017-3)
Guldeline Reference Number Guidelin	e Study Name	MRID Number	Submitter	Status	Note
			Monsanto Compan	y OWN	ţRM
		199A	Mousanto Compan	y OWN	tRM
		**	Monsanto Compan	own Own	IRM
		S	Monsanto Compan	own	1RM
		2000 2000 2000 2000 2000 2000	Monsanto Compar	own	IRM
Signature 1. am	the and Dance years in the audioble Substitution	termina termina et la compaña de la comp	Name and Title J. Auslin Burns, Ph.D. Regulatory Affairs Ma	Date December 17, 2009	1,000

EPA-Form 8570-35 (9-97) Etectronic and Paper versions available. Submit only Paper version.

Public File Copy

07-CR-192E-2

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address,

	DATA MATRIX			
Date: December 17, 2009		EPA Reg. N	Io./File Symbol: 524-551	Page 42 of 57
Applicant's/Registrant's Name & Address:				
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, N			MON 88017	
ngredient B.t. Cry3Bb1 protein and the genetic nuterial (vector)	tor ZMIR39) necessary for its production in eve	nt MON 88017 com (OECD Uni	que Identifier: MON-88Ø17	-3)
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
		Monsanto Company	OWN	IRM
		Monsanto Company	OWN	IRM
		Monsanto Company	own	tRM
		Monsanlo Company	OWN	Tolerance Exemption
		Monsanto Company	OWN	Tolerance Exemption
Signature	J.	lame and Title Austin Burns, Ph.D. Legulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Dale: December 17, 2009			EPA Re	g. No./File Symbol: 524-551	Page 43 of 57
Applicant's/Registrant's Name &				as acceptance or acceptance	
	Lindbergh Blvd., St. Louis, MO 631		Product		
	in and the genetic material (vector ZMIF	The state of the s	cnt MON 88017 com (OECD	Unique Identifier: MON-8801	
Guideline Reference Number	Guideline Sludy Name	MRID Number	Submitter	Stalus	<u>Note</u>
			Monsanto Company	OWN	Tolerance Exemption
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
			Monsanto Company	OWN	Inert Ingredient
		en e	Monsanto Company	оwи	Inert Ingredient
Signature J. an			Name and Title I. Austin Burns, Ph.D. Regulatory Affairs Manage	Date December 17, 2009	

EPA form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, Including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 f M Street, S.W., Washington, DC 20460. Do not send the form to this address,

40 f M Street, S.W., Washington, DC 20460. Do not send the form to this address,					<u> </u>
	TA MATRIX				
Date: December 17, 2009			EPA Reg. No./F	ite Symbol: 524-551	Page 44 of 57
Applicant's/Registrant's Name & Address:					
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				N 88017	
Ingredient B.t. Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary f			(OECD Unique)		- 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1
Guideline Reference Number Guideline Study Name	MRID Number	Submitter		Status	Note
		Monsanto Comp	any	OWN	Inert Ingredient
		Monsanto Comp	any	OWN	Inert Ingredient
	· - -	Monsanto Comp	pany	OWN	tnert Ingredient
		Monsante Comp	any	Own	Inert Ingredient
		Monsanto Comp		OWN	Inert Ingredient
Signature CONTROL Signature EPA Form 857(135 (9-97) Electronic and Paper versions available. Submit only Paper versions.		Name and Title J. Austin Burns, Ph.D. Regulatory Affairs M	D	ate Jecember 17, 2009	offic File Copy

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address,

401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.			
DATA MATR	IX		
Date: December 17, 2009		EPA Reg. No./File Symbol: 524-551	Page 45of 57
Applicant's/Registrant's Name & Address:			
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 88017	
Ingredient B.t. Cry3Bb1 protein and the genetic material (vector ZMIR39) necessary for its product		(OECD Unique Identifier: MON-886	
Guideline Reference Number Guideline Study Name MRtD Num	ber Submitter	Status	Note
	Monsanto Com		tnert Ingredient
	Monsanto Com	pany OW	Inert Ingredient
	Monsanto Com	pany OWN	Terms & Conditions
	Monsanto Com		Terms & Conditions
Signature A an	Name and Title J. Austin Burns, Ph.D Regulatory Affairs	Manager	ubija Filo Carri

EPA Form 8573-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting builden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			_,
Date: December 17, 2009			 EP/	A Reg. No./File Symbol: 68467-5	Page 46 o f57
Applicant's/Registrant's Name &					
	Lindbergh Blvd., St. Louis, MO 63167			duct: Herculex® RW Insect Pr	
	Insecticidal Crystal protein and the genetic		77 (20 Company of Comp		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		* !			
			68467	PER	
		시 			
			68467	PER	
		· · · · · · · · · · · · · · · · · · ·	0407	TER -	
		* #		Ì	
		* 25	68467	PER	
					10000000 0000000 000000000000000000000
		<u></u>	68467	PER	
		w _a			
			68467	PER	
				00000000	
G		<u></u>	68467	PER {	·
Signature	n-		Name and Title	Date December 17, 2009	
1- W	·VI		f. Austin Burns, Ph.D. Regulatory Affairs Manage		
04 5 05 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	ic and Paner veretons available. Submit only		1/2	Public File C	<u> </u>

EPA Form 8570 35 (9-97) Electronic and Paper versions available. Submit only Paper version.

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the Instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DAT	A MATRIX			
Date: December 17, 2009				EP.	A Reg. No./File Symbol; 68467-5	Page 47 of 57
Applicant's/Registrant's Name Monsanto Company, 800 N	V. Lindbergh Blvd., St. Louis,			Pro	duct: Herculex® RW Insect P	rotection
TO THE STATE OF TH		d the genetic material nece	25		62) in corn (OECD Identifier: DAS	S-59122-7)
Guideline Reference Number	Guideltne Study Name		MRtD Number	Submitter	Status	Note
			A section of the sect	68467	PER	
				68467	PER	
				68467	PER	
				68467	PER	
			() ()	68467	PER	
Signature 1.0	w-			Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Manage	Date Dccember 17, 2009	

EPA Form 8570-35/(9-97) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	DATA MATRIX			
Date: December 17, 2009		EPA Re	eg. No./File Symbol: 68467-5	Page 48 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product	: Herculex® RW Insect Pr	otection
ngredient B.t. Cry34/35Ab1 Insecticidal Crystal protein and the genetic materia	I necessary for its production	n (plasmid insert PHP17662)	in corn (OECD Identifier: DAS	-59122-7)
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
		68467	PER	
		68467	PER	* -
		68467	PER	
		68467	PER	
		68467	PER	
Signature A Form 85/0-35 (9-97) Electronic and Paper versions available. Submit only Paper	J. R	ame and Title Austin Burns, Ph.D. egulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-85 (9-97) Electronic and Paper versions available. Submit only Paper version.

€EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 f M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Date: December 17, 2009			EPA Re	g. No,#File Symbol: 68467-5	Page 49 of 57
Applicant's Registrant's Name & Monsanto Company, 800 N	k Address: . Lindbergh Blvd., St. Louis, MO 63167		Product	: Herculex® RW Insect Pi	rotection
Ingredient B.t. Cry34/35Ab	1 Insecticidal Crystal protein and the genetic mate	rial necessary for its production	n (plasmid insert PHP17662)	in corn (OECD Identifier: DAS	-59122-7)
Guideline Reference Number	Guideline Study Name	. MRID Number	Submitter	Status	Note
			68467	PER	
		_	68467	PER	
			68467	PER	
			68467	PER	- 2027 - V
		resident som en	68467	PER	
4.000	<u> </u>]]	Name and Title . Austin Burns, Ph.D. Regutatory Affairs Manager	Date December 17, 2009	
Jan	Onle and Paner versions available. Submit only Pa]]	Vanie and Title . Austin Burns, Ph.D.	Date	onv

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.26 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MATRIX				
Date: December 17, 2009			EPA Reg. No	o./File Symbol: 68467-5	Page 50of 57
Applicant's/Registrant's Name & Address:					
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167			···	erculex® RW Insect Pr	
Ingredient B.t. Cry34/35AbI Insecticidal Crystal protein and the genetic material		#2000 2002	53		25083 - 50
Guideline Reference Number Guideline Study Name	MRID Number	Submitter		Status	Note
		*04**	ļ	n=n	
		68467	335 335 335	PER	- 100 E
		1		,	
		60160		nen.	
		68467		PER	
		68467	Į	PER	
			ļ	į	
		68467		PER	
	<u> </u>	68467		PER	
Signature		Name and Title		Date	
Jan		J. Austin Burns, Ph.D. Regulatory Affairs Ma		December 17, 2009	
		Licentalory Atlants Ma	inagei		

EPA Form \$570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

€ EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 f37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

401 M Street, S.W., Washington, DC 20460. Do not send the form to this				
	DATA MATRIX			
Date: December 17, 2009		EPA Reg. N	No./File Symbol: 68467-5	Page 51 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63	167	Product:	Herculex® RW Insect Pr	otection
Ingredienl B.t. Cry34/35Ab I Insecticidal Crystal protein and the gen		(plasmid insert PHP17662) in c	orn (OECD Identifier: DAS-	-59122-7)
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
		68467	PER	
		68467	PER	<u>.</u>
		68467	PER	
		68467	PER	
		68467	PER	<u>.</u>
Signature Lan	J. A	me and Title Austin Burns, Ph.D. gulatory Affairs Manager	Date December 17, 2009	

EPA Form §570/-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 f37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

	D	ATA MATRIX				
Date: December 17, 2009				EPA Reg. No.t	File Symbol: 68467-5	Page 52 of 57
Applicant's/Registrant's Name &						
Monsanto Company, 800 N.	Lindbergh Blvd., St. Louis, MO 63167			Product: Her	culex® RW Insect Pro	otection
Ingredient B.t. Cry34/35Ab1	Insecticidat Crystat protein and the genetic material no	cessary for its product	ion (ptasmid insert PHI	P17662) in corn	(OECD Identifier: DAS-	59122-7)
Guideltne Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
		1	68467		PER	
			68467		PER	
			68467		PER	
			68467		PER	
			68467		PER	
Signature A. a	n-	į	Name and Title J. Austin Burns, Ph.D. Regulatory Affairs Ma	ļī	Date December 17, 2009	

EPA Form 8570-85 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

)

SEPA UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.	ROTECTION AGENCY	Form Approved OMB No. 2070-0060	IB No. 2070-006
Washington, D.C. 20460	0460		
Paperwork Reduction Act Notice: The public reporting burden for this collection of Information is estimated to average 0.25 hours per response for registration activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.	ge 0.25 hours per response for necessary forms. Send comm tion Management Division (2 f	registration activities and 0 ents regarding the burden e 37), U.S. Environmental Pro	25 hours per stimate or any slection Agency
DATA MATRIX			
Dale: December 17, 2009	EPA Reg. N	EPA Reg. No./File Symbol: 68467-5	Page 53 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Bivd., St. Louis, MO 63167	Product	Product: Herculex® RW Insect Protection	rotection
Ingredient B.t. Cry34/35Ab1 Insecticidal Crystal protein and the genetic material necessary for its production (plasmid insert PHP17662) in corn (OECD Identifier: DAS-59122-7)	lasmid insert PHP17662) in co	om (OECD Identifier: DAS	-59122-7)
Guideline Reference Number Guideline Study Name MRID Number	Submilter	Slatus	Nole
	68467	AEG	: i
	68467	ਬੁਰ	
	68467	RER	
	68467	NB4	
	68467	Ned	
Signature A W	Name and Titte J. Austin Burns, Ph.D. Regulatory Affairs Manager	Date December 17, 2009	
પ્લ Paper versions available. Submit only Paper version.		Public File Copy	Ado

)

`}

Page 129 of 175

07-CR-192E-2

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including lime for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MATRIX			
Date: December 17, 2009		EPA Re	g. No./File Symbol: 68467-5	Page 54 of 57
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product	Herculex® RW Insect Pr	otection
Ingredient B.r. Cry34/35Ab1 Insecticidal Crystal protein and the genetic or	naterial necessary for its production	(plasmid insert PHP17662) i	n corn (OECD Identifier: DAS-	-59122-7)
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
		68467	PER	
		68467	PER	
		68467	PER	
	-	68467	PER	
		68467	PER	<u></u>
Signature A. av	J.	ame and Title Austin Burns, Ph.D. egulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570-35/(9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060

€EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the Instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address,

age 55 of 5
tion
22-7)
Note
_

EPA Form 8579 35 (9-97) Electronic and Paper versions avaitable. Submit only Paper version.

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Nottce: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			-
Date: December 17, 2009			EPA Reg.	No./File Symbot: 68467-5	Page 56 of 57
Applicant's/Registrant's Name & Monsanto Company, 800 N.	Address: Lindbergh Blvd., St. Louis, MO 6316	67	Product:	Herculex® RW Insect Pr	otection
Ingredient B.t. Cry34/35Ab1	Insecticidat Crystal protein and the general	tic material necessary for its production (plasmid insert PHP17662) in	corn (OECD Identifier: DAS-	-59122-7)
Guideline Reference Number	Guidefine Study Name	MRID Number	Submitter	Status	Note
			68467	PER	
			68467	PER	
			68467	PER	
			68467	PER	<u> </u>
			68467	PER	
Signature I av		J. A	me and Title ustin Burns, Ph.D. rulatory Affairs Manager	Date December 17, 2009	

EPA Form 8570/35 (9-97) Electronic and Paper versions available. Submit only Paper version.

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	ngton, DC 20460. Do not send the form to this ac	DATA MATRIX		TH	
		PAIN MAINA			T
Date: December 17, 200	09_		EPA Reg.	No./File Symbol: 68467-5	Page 57 of 57
Applicant's/Registrant's Na				1000 00 00 00 00 00 00 00 00 00 00 00 00	
	0 N. Lindbergh Blvd., St. Louis, MO 6316	<u> </u>		Herculex® RW Insect Pr	T- T
Ingredient B.t. Cry34/3	5Ab1 Insecticidal Crystal protein and the genet	ic material necessary for its production	(plasmid insert PHP17662) in	corn (OECD Identifier: DAS	-59122-7)
Guldeline Reference Numb	per Guideline Study Name	MRID Number	<u>Submitter</u>	Stalus	Nole
				1	
			68467	PER	
				1	
			PSP 95327	2000000	
		*	68467	PER	
		ļ			·
				1	
			20020 VI 201200 1500200 VI 2012000		
Signature		INA	me and Title	Date	
	~ .		me and 1 the Austin Burns, Ph.D.	December 17, 2009	
UG			gulatory Affairs Manager	,	
			2 1	B. M. Ell. B	

EPA Form 8\$70-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

SECTION II

)

1

SUMMARY OF THE APPLICATION

Monsanto Company and Dow AgroSciences (Dow) have used conventional breeding techniques to develop the combined trait corn product MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax). This combined trait corn product is comprised of six PIPs encoded by four independent events that have each undergone safety assessments by EPA. Each of these four events as well as the SmartStax combined trait product has a separate Section 3 registration with the EPA. Permanent tolerance exemptions are in place for each of the six PIP and two inert marker proteins present in the combined trait product, SmartStax. EPA completed the safety and environmental assessment by of SmartStax leading to the Section 3 registrations, 524-581 and 68467-7, in July, 2009.

Currently, the majority of U.S. com production utilizing PIP-containing com requires a 20% non-insect protected (referred to as non-PIP or non-Bt) discrete structured refuge for insect-protected Bt com. The majority of these products produce a single Bt toxin mode of action (insect control). The strategy to use two or more effective doses with differing modes of action (so-called pyramiding) as an effective way to combat resistance development is supported by academics and regulators as the most effective strategy to foster the durability of insect-protected biotech crops. SmartStax produces three Bacillus thuringiensis (Bt) protein toxins each with independent modes of action against lepidopteran com pests, and two Bt protein toxins with independent modes of insect control against com rootworms. Each insecticidal mode of action provides an effective dose against these pests. Thus, SmartStax represented a step-change in insect control and insect resistance management (IRM) for com pests, providing multiple effective modes of action for the control of both above-ground lepidopteran pests and the below-ground com rootworm (CRW) complex, enabling a significant reduction in the required refuge area (5%) in the U.S. Corn Belt compared with single toxin products (20%).

The IRM conditions of registration for SmartStax under registrations 524-581 and 68467-7 require growers in the U.S. Corn Belt (non-cotton growing areas) to plant 5% of their corn acres with a non-Bt common insect refuge for every 95% of their acres of SmartStax. The non-Bt 'common' refuge supports the production of non-resistant adult insects for both the lepidopteran and corn rootworm pests to mate with the respective surviving insects emerging from SmartStax plants, and thus serves as a refuge for both lepidopteran and corn rootworm pests. This non-Bt refuge corn can be placed as a discrete area, either as infield strips, perimeter rows, adjacent block, or as a separate block within 1/2 mile from the SmartStax field. The specific refuge requirements are defined according to the prevailing pests in a given region, and whether plantings occur in major cotton growing regions.

Extensive laboratory and field studies, and conservative mathematical modeling, showed that even with the 5% structured refuge, the rate of resistance evolution should be at least three times slower for SmartStax than existing single toxin products utilized with a 20%

Monsanto Company 07-CR-192E-2 Page 134 of 175

refuge. Given the significant improvements in insect control efficacy and spectrum, reduction in refuge, overall improvements in yields and potential for elimination of soil-applied pesticides, SmartStax corn has the potential to produce sizable pecuniary and non-pecuniary benefits for farmers and the environment. The multiple effective dose strategy is a central component of the durable IRM refuge strategy for SmartStax, using a 5% refuge in any field configuration.

Although the SmartStax registration provided data and modeling information to support deployment of various 5% discrete structured refuge option in the Corn Belt, Monsanto and Dow have investigated alternative refuge designs over many years. This includes an interspersed refuge approach (commonly referred to as a 'seed mix', or 'refuge in a bag'), in which a fixed amount of non-Bt seed would be included within each bag of SmartStax seed corn to create a interspersed distribution of non-Bt refuge plants among the SmartStax corn plants across a field. Seed mixes of Bt and non-Bt seed have been recognized as a possible insect resistance management (IRM) strategy for Bt crops for almost two decades because of the value of having an IRM strategy implemented by the technology provider rather than growers. This removes the issue of grower compliance with the IRM strategy and ensures that a refuge will be present within every Bt crop field. Benefits of an interspersed refuge via seed mixes from an IRM perspective include:

- · Consistent percentage of non-Bt plants in every Bt field
- An interspersed in-field distribution of non-Bt plants will be particularly beneficial for very large fields
- Reduced probability of mating between Bt-resistant adults
- · Appropriate choice of refuge hybrid ensured
- Identical management of Bt and refuge plants
- No additional insecticide use on refuge plants
- Higher adoption of pyramided varieties, increasing the durability of all Bt traits

A major hindrance to enabling the development and deployment of an interspersed refuge structure in the past has been the minimum 20% refuge size necessary to ensure durability (time to resistance development) of single dose products. In-field refuges above 5% caused unacceptable total field yield losses in an interspersed in-field refuge structure. With the development of SmartStax corn containing two- and three- effective insecticide modes of action against targeted pests, the substantial increase in durability supported a reduction in the refuge from 20% to 5%. The durability of SmartStax with a 5% refuge for both above-ground and below-ground pests also strongly supports a 5% interspersed in-field refuge structure, as delivered by planting a seed mix refuge.

The central need for an interspersed refuge – as with any refuge strategy, is that it supports sufficient populations of susceptible target insects while enabling mixing of these insects with any resistant insects surviving in Bt corn fields. Compared with a block refuge, the novel characteristic of a seed mix is the interspersed nature of Bt and non-Bt plants within in a field. This spatial distribution will enhance the mixing of adult insects coming from Bt and non-Bt plants, ensuring that any resistant insects surviving on Bt plants will

Monsanio Company 07-CR-192E-2 Page 135 of 175

encounter susceptible insects coming from non-Bt plants, which will be beneficial for IRM. However, this spatial distribution of plants in a field also could increase the likelihood that larval insects may move between Bt and non-Bt plants because all non-Bt plants will have neighboring Bt plants. Thus, it is important to quantify the impacts of this larval movement on the refuge function within an interspersed refuge from a seed mix.

1

j

1

Specifically, two criteria need to be met to confirm that a 5% seed mix refuge is as effective as current refuge options for SmartStax. First, the seed mix should not lead to a biologically significant increase in sub-lethal exposure of larvae to the Bt toxins that could increase selection for Bt resistance. This could occur either through early instar larvae of the target pests moving from Bt plants to non-Bt plants after sub-lethal exposure, or by larvae moving from non-Bt to Bt plants as larger, more Bt-tolerant instars. Assessment of this issue requires examining the susceptibility of larvae of different ages to the proteins in SmartStax. Based on extensive data, the expectation is that the enhanced toxicity conferred by the multiple effective modes of action of SmartStax will make it unlikely that larvae will be able to move and survive in this way, particularly for the highly susceptible lepidopteran target pests. Second, the non-Bt plants in the interspersed field seed mix must support sufficient susceptible pest insects to be an adequate refuge. This can be assessed through direct surveys of pest population density on the non-Bt plants, together with appropriate mathematical modeling.

To this aim, this registration application provides data collected over the past three years assessing the efficacy and value of an interspersed 5% in-field refuge option, via a seed mix containing an admixture of 5% non-Bt refuge seed + 95% SmartStax seed, as an additional refuge strategy for SmartStax corn in the U.S. Corn Belt. Details of these data and analyses are presented in Volume 2 of this submission. The supporting data and information included in this request include (1) data on larval movement and survival in a 5% interspersed in-field refuge for the key lepidopteran (European corn borer (ECB) and southwestern corn borer (SWCB)) and coleopteran target pests (primarily western corn rootworm (WCR) and secondarily northern corn rootworm (NCR)); (2) mathematical modeling to demonstrate the acceptable risk of a interspersed 5% in-field refuge strategy compared to existing refuge strategies; (3) data on the efficacy of a 5% interspersed refuge against the target pests, and the impact of the non-Bt plants in the interspersed refuge on overall yield; (4) criteria are described for ensuring and verifying a consistent seed mix percentage during the manufacturing process; and additionally, (5) information outlining the benefits for growers, the public, and environment that would result from the addition of an interspersed refuge option for SmartStax (Volume 3 of this submission).

Presented in Volume 2, laboratory and field data indicate that a 5% seed mix will provide an effective refuge for SmartStax for ECB, SWCB, and the CRW species. For all of these pests, the non-Bt plants in a 5% seed mix consistently supported large populations of susceptible insects, while the SmartStax plants had few or no survivors. Highly conservative mathematical modeling shows that an interspersed refuge strategy will ensure the durability of SmartStax corn and will provide comparable or greater durability than 5% structured refuge in the Corn Belt, depending upon the nature of compliance with the structured refuge, and greater durability than single Bt products with a 20% refuge.

Monsanto Company 07-CR-192E-2 Page 136 of 175

Furthermore, this approach will provide yields comparable to current structured refuge systems but with greater convenience and reduced insecticide use on the refuge, thereby bringing additional benefits beyond those of SmartStax with 5% discretely structured refuge.

Presented in Volume 3, the benefits to growers, the environment, and to society at large will be realized by the addition of an interspersed 5% in-field refuge option for SmartStax. Under all 5% refuge options (the strip or block refuge strategy supported in SmartStax registrations 524-581 and 68467-7, and the interspersed 5% in-field refuge proposed with this application), SmartStax represents significant value to U.S. farmers. There are unique benefits to a SmartStax 5% interspersed refuge above those provided by discrete strip or block refuges. These include substantial non-pecuniary grower benefits, environmental benefits, and improved compliance with IRM requirements. Enabling growers to broadly plant SmartStax corn with an interspersed in-field refuge will support:

- Reduction or potential elimination of application of soil-applied insecticides
- Reduce potential for corn rootworm insecticides in ground or surface water
- Reduce farm worker exposure to organophosphate insecticides, accidental insecticide spills, and insecticide carryover effects
- · Increase simplicity, flexibility, and time savings associated with planting the refuge
- Guarantee grower compliance with IRM requirements

1

 Provide incentive to growers to switch to pyramided Bt technology, improving durability of Bt corn technology

This request for a registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 (SmartStax) will allow an in-field refuge structure in which the non-Bt refuge plants are interspersed within the SmartStax field. This type of interspersed in-field refuge would be implemented by growers planting a defined seed mixture comprised of PIP (SmartStax) seed with a fixed amount of non-Bt (refuge) seed. In addition, the interspersed refuge would only be implemented via planting a seed-mixture manufactured by the technology provider (registrants) and appropriately licensed seed producer affiliates. This non-Bt refuge would be complementary, but distinct from, the refuge structures currently allowed under SmartStax registrations 524-581 and 68467-7 (in-field strips, rows, or blocks).

The seed mix itself is not within scope of the EPA regulations for PIPs because this registration request (addition of unregulated non-PIP seed materials to PIP seed com prior to planting) has not changed the underlying PIP (SmartStax). It is the plant incorporated protectant (pesticide) and associated genetic material within the plant that is regulated, not the plant itself of the seed mix, variety, or delivery mechanism of the seed into the field. This position has been previously clarified by the Agency. EPA has defined PIPs as "Pesticidal substances and the genetic material needed to produce them by plants that have been genetically modified so the plant is protected from certain insect pests. For example, scientists can take the gene for the Bt pesticidal protein from the bacterium, and introduce that gene into the plant's own genetic material. Then the plant manufactures the substance that destroys the pest. EPA regulates the protein and its genetic material, but not the plant itself...:" http://www.epa.gov/pesticides/ees/tool/decisiontree/main.htm (accessed 11-30-

Monsanto Company 07-CR-192E-2 Page 137 of 175

2009). Additionally, the scope of this registration request is only partially analogous to other registration requests involving corn seed mixtures of two different PIPs, whereas the scope of this present request involves a single PIP product that is currently registered (524-581 and 68467-7) for other in-field refuge arrangements. Thus, for this request, the infield relationship of SmartStax to the non-PIP refuge does not change the composition of the SmartStax PIP (the pesticidal proteins and associated genetic material listed in the Confidential Statement of Formula). Additionally, the overall field composition of SmartStax with a 5% interspersed in-field refuge would be the same as that of a 5% infield strip row refuge configuration allowed in registrations 524-581 and 68467-7. The IRM structure described herein does not involve the utilization of any additional PIPs or change to the confidential statement of formula (CSF) or label ingredients, but instead allows the currently mandated refuge in the field to be interspersed within the field as opposed to being placed in rows within or adjacent to the field. The mechanism of ensuring compliance with the interspersed refuge option is by limiting grower use of this option to planting seed mixes produced by the registrants and properly enabled, licensed seed producers.

In developing an IRM strategy for SmartStax using a structured refuge that is interspersed within the field, the data must address aspects related to proximity of the PIP and non-PIP plants, insect pest presence and biology, and productivity of adult insects from individual plants within the interspersed in-field refuge compared to other forms of structured refuges. The IRM properties of SmartStax, particularly the multiple effective modes of action against both above and below-ground pests, open the opportunity to add options for an interspersed in-field refuge to the current approved structured refuge options. Such an in-field option and the delivery of the option to growers as a seed mix would strengthen the existing IRM program by ensuring that a refuge is present in every SmartStax corn field deploying this option and removing concerns about grower compliance with refuge requirements. EPA has previously recognized that multiple refuge options for Bt corn and cotton products are essential to prevent the rapid onset of resistance. As additional data have been developed on IRM, EPA has granted registrants amended registrations to enhance farmers' refuge options and overall compliance. Currently, SmartStax com non-Bt refuges can be planted as in-field four row strips, perimeters, in-field blocks, and separate blocks adjacent to the Bt field. Similarly, in the case of a dual effective mode of action cotton product like Bollgard II (MON 15985, EPA Reg. No. 524-522), either a structured refuge or a so-called natural refuge (no non-Bt cotton refuge), may be utilized. In all of these registration amendments, the principle goal was to ensure a strong IRM program. The EPA has ample precedence amending Bt crop registrations to allow for optimization of size, structure, or placement of the refuge structure in Bt crops, as well as different use instructions.

Therefore, Monsanto and Dow are hereby requesting a registration for the plant-incorporated protectant, *Bacillus thuringiensis* Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1 and Cry35Ab1 Proteins and the Genetic Materials (Vectors PV-ZMIR245, PHP8999, PV-ZMIR39, and PHP17662) necessary for their production in MON 89034 × TC1507 × MON 88017 × DAS-59122-7, with an interspersed in-field refuge configuration. The interspersed refuge would be implemented via a seed mixture in bags of seed corn

1

Monsanto Company 07-CR-192E-2 Page 138 of 175

consisting of 5% non-Bt corn along with 95% SmartStax corn. Seed mixtures to be planted under this option would only be prepared by seed producers licensed by the registrants to ensure consistency and provide adequate refuge in the field. Studies and information supporting the request are provided in Volumes 1, 2, and 3 of this submission.

Monsanto Company

07-CR-192E-2

SECTION III

PRODUCT LABEL

The subject of this application is for the combined plant-incorporated protectants, *Bacillus thuringiensis* (Bt) Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins and the genetic material necessary for their production in com (PV-ZMIR245, PHP8999, PV-ZMIR39, PHP17662) produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 to allow an additional IRM interspersed in-field refuge configuration. This refuge configuration is enabled by a seed-mixture containing PIP and non-PIP seed, and is limited to use in the U.S. Com Belt. Five copies of the proposed label for the registration of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, to support an interspersed infield refuge are attached.

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn (Alternate Brand Name GenuityTM SmartStaxTM)

(OECD Unique Identifier: MON-89Ø34-3 × DAS- Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients: Bacillus thuringiensis Cryl A. 105 protein and the genetic material neces ZMIR245) for its production in corn event MON 89034		
Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessar ZMIR245) for its production in corn event MON 89034		
Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production in corn event TC1507		
Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessal ZMIR39) for its production in corn event MON 88017		
Bacillus thuringiensis Cry34Ab1 protein and the genetic material necess PHP17662) for its production in corn event DAS-59122-7		
Bacillus thuringiensis Cry35Ab1 protein and the genetic material necess PHP17662) for its production in corn event DAS-59122-7		
Inert Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and material necessary (vector PV-ZMIR39) for its production in corn event	MON 880)17 💛 '
PAT protein (phosphinothricin acetyl transferase) and the genetic materic (vectors PHP17662 and PHP8999) for its production in corn event TC15 DAS-59122-7* *Maximum percent (wt/wt) of dry forage	507 and	
KEEP OUT OF REACH OF CHILDREN		333399
CAUTION		3 3 3
NET CONTENTS	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	,,,,,
EPA Registration No. 524-XXX EPA Establishment No. 524-MO-002	3333 3333 333	3 3 3 3
Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167		3) 2) 3) 3) 3 3) 4 3 6 3233

ì

0101

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by a Grower/IRM Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products. A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product's refuge configuration is interspersed within the field and is allowed only by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed, and is limited to use in the U.S. Corn Belt.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed comunder this registration; however, seed propagation over 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year would utilize the discrete refuge options for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under EPA registration 524-581.

Ability to plant this interspersed refuge configuration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is based on geography and the insect pressure present in various locations. In non-cotton growing regions and in cotton growing regions where corn earworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under GenuityTM SmartStax registration 524-581), a seed mix refuge option is allowed. Planting SmartStax corn in regions prohibiting an interspersed refuge option is still available to growers under registration 524-581. The interspersed refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × TC1507 × MON 88017 × DAS-59122-7. The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each unit of seed corn.

The interspersed refuge option can only be used by planting seed corn specifically generated by seed producers licensed by the registrant. With this option, the refuge seed may not be treated with seed-applied insecticides for Corn Rootworm (CRW) control, and the refuge plants may not be treated with insecticides for Lepidopteran pest or CRW

Monsanto Company

1

07-CR-192E-2

[™] Genuity and SmartStax are trademarks of Monsanto Technology LLC.

control unless the entire field is treated. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

A schematic of the interspersed refuge from planting a seed mix of 95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed with 5% non-PIP com is shown below. This option is not allowed in cotton-growing regions where corn earworm is a significant pest (i.e. the regions where the minimum refuge size is 20% under SmartStax registration 524-581).

Interspersed Refuge

95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and 5% non-PIP refuge

The table below summarizes the interspersed refuge option for each region based on the planting of MON $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$ seed mixture in cotton or non-cotton growing regions and the insect pressure present in those locations.

Region	Planting Refuge as seed mix allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW, and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	No
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW, and MCRW are not significant. NM, AZ, CA, NV	Yes
Non-cotton growing where WCRW, NCRW, and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin	Yes

City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton) Non-cotton growing where Yes WCRW, NCRW, and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)

Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA	Accepted:		/ /	1
		-	_	-

4

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn (Alternate Brand Name GenuityTM SmartStaxTM)

(OECD Unique Identifier: MON-89Ø34-3 × DAS- Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

MON-88017-3 × DAS-59122-7)
Active Ingredients: Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0026%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59I22-7≤0.0042%*
Inert Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017 ———————————————————————————————————
CAUTION
NET CONTENTS
EPA Registration No. 524-XXX EPA Establishment No. 524-MO-002
Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by a Grower/IRM Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products. A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product's refuge configuration is interspersed within the field and is allowed only by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed, and is limited to use in the U.S. Corn Belt.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn under this registration; however, seed propagation over 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year would utilize the discrete refuge options for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under EPA registration 524-581.

Ability to plant this interspersed refuge configuration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is based on geography and the insect pressure present in various locations. In non-cotton growing regions and in cotton growing regions where come arworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under GenuityTM SmartStax registration 524-581), a seed mix refuge option is allowed. Planting SmartStax corn in regions prohibiting an interspersed refuge option is still available to growers under registration 524-581. The interspersed refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × TC1507 × MON 88017 × DAS-59122-7. The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each unit of seed corn.

The interspersed refuge option can only be used by planting seed corn specifically generated by seed producers licensed by the registrant. With this option, the refuge seed may not be treated with seed-applied insecticides for Corn Rootworm (CRW) control, and the refuge plants may not be treated with insecticides for Lepidopteran pest or CRW

Monsanto Company

j

07-CR-192E-2

ты Genuity and SmartStax are trademarks of Monsanto Technology LLC.

control unless the entire field is treated. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

A schematic of the interspersed refuge from planting a seed mix of 95% MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 seed with 5% non-PIP corn is shown below. This option is not allowed in cotton-growing regions where corn earworm is a significant pest (i.e. the regions where the minimum refuge size is 20% under SmartStax registration 524-581).

Interspersed Refuge

95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and 5% non-PIP refuge

Monsanto Company

07-CR-192E-2

The table below summarizes the interspersed refuge option for each region based on the planting of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed mixture in cotton or non-cotton growing regions and the insect pressure present in those locations.

Region	Planting Refuge as seed mix allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW, and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	No
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW, and MCRW are not significant: NM, AZ, CA, NV	Yes
Non-cotton growing where WCRW, NCRW, and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin	Yes

City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton) Yes Non-cotton growing where WCRW, NCRW, and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)

Corn Insects Controlled or Suppressed

European com borer (ECB)
Southwestern com borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

Monsanto Company 07-CR-192E-2 Page 151 of 175

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted:	/	/
	-	

Plant-Incorporated Protectant Label MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn (Alternate Brand Name GenuityTM SmartStaxTM)

(OECD Unique Identifier: MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

MON-88Ø17-3 × DAS-59122-7)
Active Ingredients: Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0026%*
Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary (vector PV-ZMIR245) for its production in corn event MON 89034≤ 0.0053%*
Bacillus thuringiensis Cry1F protein and the genetic material necessary (vector PHP8999) for its production in corn event TC1507≤ 0.0012%*
Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017≤ 0.0079%*
Bacillus thuringiensis Cry34Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7≤ 0.0194%*
Bacillus thuringiensis Cry35Ab1 protein and the genetic material necessary (vector PHP17662) for its production in corn event DAS-59122-7≤ 0.0042%*
Inert Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary (vector PV-ZMIR39) for its production in corn event MON 88017 ≤ 0.0052%*
PAT protein (phosphinothricin acetyl transferase) and the genetic material necessary (vectors PHP17662 and PHP8999) for its production in corn event TC1507 and DAS-59122-7≤ 0.00045%* *Maximum percent (wt/wt) of dry forage
KEEP OUT OF REACH OF CHILDREN
CAUTION
NET CONTENTS
EPA Registration No. 524-XXX EPA Establishment No. 524-MO-002
Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by a Grower/IRM Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects com crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products. A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product's refuge configuration is interspersed within the field and is allowed only by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed, and is limited to use in the U.S. Corn Belt.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn under this registration; however, seed propagation over 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year would utilize the discrete refuge options for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under EPA registration 524-581.

Ability to plant this interspersed refuge configuration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is based on geography and the insect pressure present in various locations. In non-cotton growing regions and in cotton growing regions where corn earworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under GenuityTM SmartStax registration 524-581), a seed mix refuge option is allowed. Planting SmartStax corn in regions prohibiting an interspersed refuge option is still available to growers under registration 524-581. The interspersed refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × TC1507 × MON 88017 × DAS-59122-7. The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each unit of seed corn.

The interspersed refuge option can only be used by planting seed com specifically generated by seed producers licensed by the registrant. With this option, the refuge seed may not be treated with seed-applied insecticides for Corn Rootworm (CRW) control, and the refuge plants may not be treated with insecticides for Lepidopteran pest or CRW

Monsanto Company

)

07-CR-192E-2

[™] Genuity and SmartStax are trademarks of Monsanto Technology LLC.

control unless the entire field is treated. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

A schematic of the interspersed refuge from planting a seed mix of 95% MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 seed with 5% non-PIP corn is shown below. This option is not allowed in cotton-growing regions where corn earworm is a significant pest (i.e. the regions where the minimum refuge size is 20% under SmartStax registration 524-581).

Interspersed Refuge

95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and 5% non-PIP refuge The table below summarizes the interspersed refuge option for each region based on the planting of MON $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$ seed mixture in cotton or non-cotton growing regions and the insect pressure present in those locations.

Region	Planting Refuge as seed mix allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW, and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	No
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW, and MCRW are not significant: NM, AZ, CA, NV	Yes
Non-cotton growing where WCRW, NCRW, and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin	Yes

1

City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton) Non-cotton growing where Yes WCRW, NCRW, and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)

ì

Corn Insects Controlled or Suppressed

European corn borer (ECB) Ostrinia nubilalis Southwestern corn borer (SWCB) Diatraea grandiosella Southern cornstalk borer (SCSB) Diatraea crambidoides Corn earworm (CEW) Helicoverpa zea Fall armyworm (FAW) Spodoptera frugiperda Stalk borer Papaipema nebris Lesser corn stalk borer Elasmopalpus lignosellus Sugarcane borer (SCB) Diatraea saccharalis Western bean cutworm (WBC) Richia albicosta Black cutworm Agrotis ipsilon

Western corn rootworm (WCRW)

Northern corn rootworm (NCRW)

Mexican corn rootworm (MCRW)

Diabrotica virgifera virgifera

Diabrotica virgifera zeae

Monsanto Company 07-CR-192E-2

Page 157 of 175

MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted:	1	/

Monsanto Company

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn (Alternate Brand Name GenuityTM SmartStaxTM)

(OECD Unique Identifier: MON-89Ø34-3 \times DAS-Ø15Ø7-1 \times MON-88Ø17-3 \times DAS-59122-7)

Active Ingredients: Bacillus thuringiensis Cry1A.105 protein and the genetic material nece ZMIR245) for its production in corn event MON 89034		
Bacillus thuringiensis Cry2Ab2 protein and the genetic material necess ZMIR245) for its production in corn event MON 89034		
Bacillus thuringiensis Cry1F protein and the genetic material necessary for its production in corn event TC1507		
Bacillus thuringiensis Cry3Bb1 protein and the genetic material necess ZMIR39) for its production in corn event MON 88017		
Bacillus thuringiensis Cry34Ab1 protein and the genetic material neces PHP17662) for its production in corn event DAS-59122-7		
Bacillus thuringiensis Cry35Ab1 protein and the genetic material neces PHP17662) for its production in corn event DAS-59122-7		
Inert Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) an material necessary (vector PV-ZMIR39) for its production in corn ever	nt MON 880)17
PAT protein (phosphinothricin acetyl transferase) and the genetic mate (vectors PHP17662 and PHP8999) for its production in corn event TCI DAS-59122-7.	1507 and	
*Maximum percent (wt/wt) of dry forage		
KEEP OUT OF REACH OF CHILDREN	92	*****
CAUTION)))))))	3 * 3 2 * 3
NET CONTENTS	, , , , ,	, , ,
EPA Registration No. 524-XXX EPA Establishment No. 524-MO-002)))))))))))))))))))) **) **) 1337) 1331
Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167		3 33

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by a Grower/IRM Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products. A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product's refuge configuration is interspersed within the field and is allowed only by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed, and is limited to use in the U.S. Corn Belt.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn under this registration; however, seed propagation over 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year would utilize the discrete refuge options for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under EPA registration 524-581.

Ability to plant this interspersed refuge configuration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is based on geography and the insect pressure present in various locations. In non-cotton growing regions and in cotton growing regions where corn earworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under GenuityTM SmartStax registration 524-581), a seed mix refuge option is allowed. Planting SmartStax corn in regions prohibiting an interspersed refuge option is still available to growers under registration 524-581. The interspersed refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × TC1507 × MON 88017 × DAS-59122-7. The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each unit of seed corn.

The interspersed refuge option can only be used by planting seed corn specifically generated by seed producers licensed by the registrant. With this option, the refuge seed may not be treated with seed-applied insecticides for Corn Rootworm (CRW) control, and the refuge plants may not be treated with insecticides for Lepidopteran pest or CRW

[™] Genuity and SmartStax are trademarks of Monsanto Technology LLC.

control unless the entire field is treated. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

A schematic of the interspersed refuge from planting a seed mix of 95% MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 seed with 5% non-PIP corn is shown below. This option is not allowed in cotton-growing regions where corn earworm is a significant pest (i.e. the regions where the minimum refuge size is 20% under SmartStax registration 524-581).

Interspersed Refuge

95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and 5% non-PIP refuge

The table below summarizes the interspersed refuge option for each region based on the planting of MON $89034 \times TC1507 \times MON 88017 \times DAS-59122-7$ seed mixture in cotton or non-cotton growing regions and the insect pressure present in those locations.

Region	Planting Refuge as seed mix allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW, and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	No
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madnid, Pemiscot, Scott, and Stoddard)	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW, and MCRW are not significant: NM, AZ, CA, NV	Yes
Non-cotton growing where WCRW, NCRW, and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin	Yes

City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, Hl, AK, TN (except the counties of Carroll, Chester, Crockett, Dver, Favette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton) Non-cotton growing where Yes WCRW, NCRW, and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)

Corn Insects Controlled or Suppressed

European com borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: __/_/_

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 88017 × DAS-59122-7

Insect-Protected, Herbicide-Tolerant Corn (Alternate Brand Name GenuityTM SmartStaxTM)

(OECD Unique Identifier: MON-89Ø34-3 × DAS- Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7)

Active Ingredients: Bacillus thuringiensis Cry1A.105 protein and the genetic material nece ZMIR245) for its production in corn event MON 89034		
Bacillus thuringiensis Cry2Ab2 protein and the genetic material necess ZMIR245) for its production in corn event MON 89034		
Bacillus thuringiensis Cry1F protein and the genetic material necessar for its production in corn event TC1507		10 10 10 10 10 10 10 10 10 10 10 10 10 1
Bacillus thuringiensis Cry3Bb1 protein and the genetic material necess ZMIR39) for its production in corn event MON 88017	117. C. S.	
Bacillus thuringiensis Cry34Ab1 protein and the genetic material nece PHP17662) for its production in corn event DAS-59122-7		
Bacillus thuringiensis Cry35Ab1 protein and the genetic material nece PHP17662) for its production in corn event DAS-59122-7	200.00	
Inert Ingredients: CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) ar material necessary (vector PV-ZMIR39) for its production in corn even	nt MON 88	017
PAT protein (phosphinothricin acetyl transferase) and the genetic mate (vectors PHP17662 and PHP8999) for its production in corn event TC DAS-59122-7. *Maximum percent (wt/wt) of dry forage	1507 and	\$.53%
KEEP OUT OF REACH OF CHILDREN))
CAUTION		3 3 3
NET CONTENTS	3 3 3 3	3 3 3 2 3
EPA Registration No. 524-XXX EPA Establishment No. 524-MO-002	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	, ,,,
Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,

DIRECTIONS FOR USE

1

)

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated pesticide(s) must be accompanied by a Grower/IRM Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 88017 × DAS-59122-7 corn, an insect resistance management plan must be implemented which includes planting of a refuge. Growers who fail to comply with the IRM requirements risk losing access to Monsanto's corn PIP products. A common refuge must be planted for both corn borers and corn rootworms. The refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. This product's refuge configuration is interspersed within the field and is allowed only by planting a licensed seed-mixture containing MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and a minimum of 5% non-PIP seed, and is limited to use in the U.S. Com Belt.

These refuge requirements do not apply to seed propagation of inbred and hybrid seed corn under this registration; however, seed propagation over 20,000 acres per county and up to a combined US total of 250,000 acres per PIP active ingredient per year would utilize the discrete refuge options for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under EPA registration 524-581.

Ability to plant this interspersed refuge configuration for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is based on geography and the insect pressure present in various locations. In non-cotton growing regions and in cotton growing regions where corn earworm is not a significant pest (i.e. the same regions where the minimum refuge size is 5% under GenuityTM SmartStax registration 524-581), a seed mix refuge option is allowed. Planting SmartStax corn in regions prohibiting an interspersed refuge option is still available to growers under registration 524-581. The interspersed refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × TC1507 × MON 88017 × DAS-59122-7. The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with the MON 89034 × TC1507 × MON 88017 × DAS-59122-7 in each unit of seed corn.

The interspersed refuge option can only be used by planting seed corn specifically generated by seed producers licensed by the registrant. With this option, the refuge seed may not be treated with seed-applied insecticides for Corn Rootworm (CRW) control, and the refuge plants may not be treated with insecticides for Lepidopteran pest or CRW

Monsanto Company 07-CR-192E-2 Page 166 of 175

[™] Genuity and SmartStax are trademarks of Monsanto Technology LLC.

control unless the entire field is treated. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

A schematic of the interspersed refuge from planting a seed mix of 95% MON 89034 \times TC1507 \times MON 88017 \times DAS-59122-7 seed with 5% non-PIP corn is shown below. This option is not allowed in cotton-growing regions where corn earworm is a significant pest (i.e. the regions where the minimum refuge size is 20% under SmartStax registration 524-581).

Interspersed Refuge

95% MON 89034 × TC1507 × MON 88017 × DAS-59122-7 and 5% non-PIP refuge

Monsanto Company

The table below summarizes the interspersed refuge option for each region based on the planting of MON 89034 × TC1507 × MON 88017 × DAS-59122-7 seed mixture in cotton or non-cotton growing regions and the insect pressure present in those locations.

Region	Planting Refuge as seed mix allowed
Cotton growing where CEW is a significant pest and WCRW, NCRW, and MCRW are not significant: NC, SC, GA, FL, TN (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), AL, MS, LA, AR, VA (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex)	No
Cotton growing where CEW is a significant pest and WCRW, NCRW, and/or MCRW are significant: TX (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), OK (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), MO (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard)	No
Cotton growing where CEW is not a significant pest and WCRW, NCRW, and MCRW are not significant: NM, AZ, CA, NV	Yes
Non-cotton growing where WCRW, NCRW, and MCRW are not significant: OR, WA, ID, MT, WY, UT, VA (except the counties of Dinwiddie, Franklin	Yes

City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), WV, PA, MD, DE, CT, RI, NJ, NY, ME, MA, NH, VT, HI, AK, TN (except the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton) Non-cotton growing where Yes WCRW, NCRW, and/or MCRW are significant: KS, NE, SD, ND, MN, IA, MO (except the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard), IL, WI, MI, IN, OH, KY, CO, OK (except the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), TX (only the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman)

Corn Insects Controlled or Suppressed

European corn borer (ECB)
Southwestern corn borer (SWCB)
Southern cornstalk borer (SCSB)
Corn earworm (CEW)
Fall armyworm (FAW)
Stalk borer
Lesser corn stalk borer
Sugarcane borer (SCB)
Western bean cutworm (WBC)
Black cutworm

Western corn rootworm (WCRW) Northern corn rootworm (NCRW) Mexican corn rootworm (MCRW) Ostrinia nubilalis
Diatraea grandiosella
Diatraea crambidoides
Helicoverpa zea
Spodoptera frugiperda
Papaipema nebris
Elasmopalpus lignosellus
Diatraea saccharalis
Richia albicosta
Agrotis ipsilon

Diabrotica virgifera virgifera Diabrotica barberi Diabrotica virgifera zeae

MON 89034 × TC1507 × MON 88017 × DAS-59122-7 is a product of Monsanto's and Dow AgroSciences' research programs, offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 5554798, 5641876, 5717084, 5728925, 5804425, 6018100, 6025545, 6051753, 6063597, 6083878, 6331665, 6489542, 6645497, 6962705, 7064249, 7227056, and 7250501.

EPA Accepted: __/_/_

SECTION IV

PRODUCT ANALYSIS

Studies and volumes addressing product analysis were previously reviewed under EPA registration 524-581. These studies are referenced by MRID in the data matrix and describe the a) human health and environmental assessment of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, b) the molecular identity of MON 89034 × TC1507 × MON 88017 × DAS-59122-7, and c) levels of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in tissues of MON 89034 × TC1507 × MON 88017 × DAS-59122-7.

07-CR-192E-2 Page 171 of 175

SECTION V

RESIDUE DATA

EPA has registered the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, and Cry34/Cry35Ab1 proteins as produced in corn. The safety of these proteins has been demonstrated and they are exempted from the requirement of a tolerance.

	Tolerance Exemption Information		
Protein	40 CFR	Date	Crop(s)
Cry1A.105	§174.502	2008	Corn
CrylF	§174.520	2001	Corn
Cry2Ab2	§174.519_	2008	Corn and Cotton
Cry3Bb1	§174.518	2004	Corn
Cry34/ Cry35Ab1	§174.506	2005	Corn

SECTION VI

NONTARGET ORGANISM DATA

Studies conducted by Monsanto to characterize the potential hazards to non-target organisms (NTOs) as a result of exposure to the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 proteins have previously been submitted to EPA and were reviewed for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under registration 524-581, and are referenced by MRID in the data matrix.

SECTION VII

TOXICOLOGY DATA

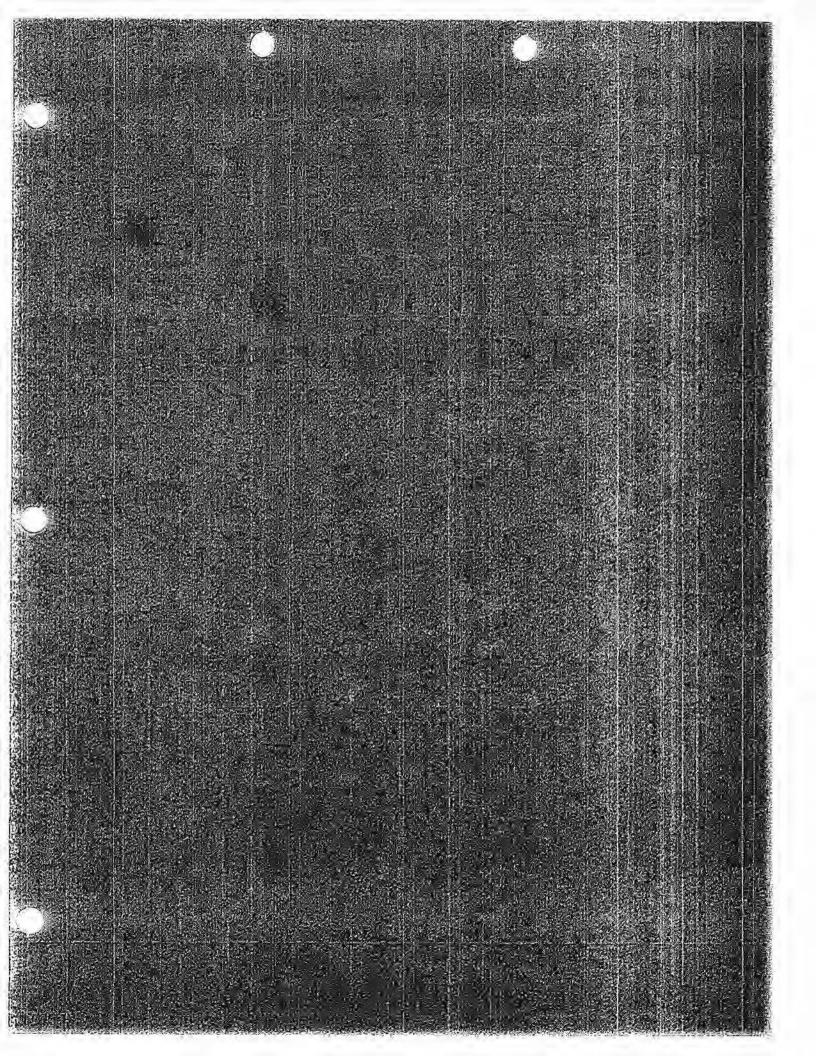
Studies conducted to assess the potential toxicity and allergenicity of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, and Cry35Ab1 and the inert proteins have previously been submitted to EPA and were reviewed for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under registration 524-581. These studies are referenced by MRID in the data matrix. Studies demonstrating functional equivalence of the *E. coli-* and plant-produced Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 PIP proteins have previously been submitted to EPA and are exempted from the requirement of a tolerance: 40 CFR §174.502, §174.519, §174.520, §174.518, and §174.506, and were reviewed for products TC1507, DAS-59122-7, MON 88017, MON 89034, and for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under registration 524-581. These studies are referenced by MRID number in the data matrix. The CP4 EPSPS and PAT proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 are classified as plant pesticide inert ingredients and are exempted from the requirement of a tolerance: 40 CFR §174.523 and §174.522, respectively, and the studies pertinent to those reviews are referenced by MRID number in the data matrix.

1

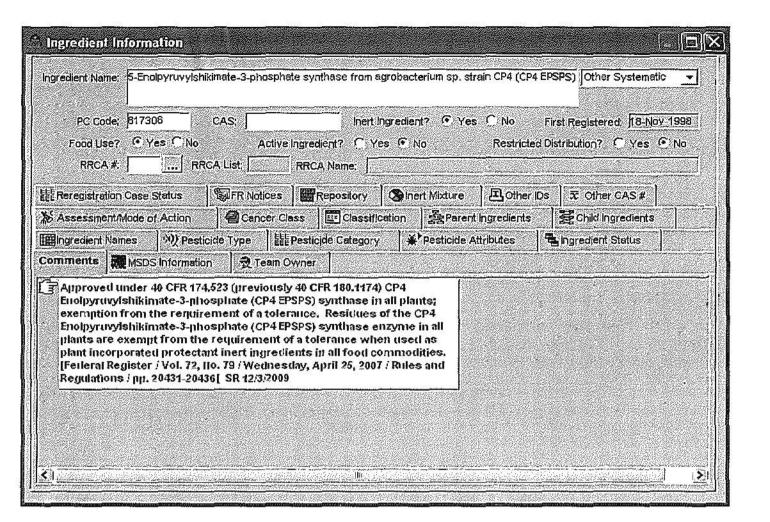
SECTION VIII

EFFICACY DATA

Studies and data demonstrating the efficacy and spectrum of insecticidal activity of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 were reviewed for MON 89034 × TC1507 × MON 88017 × DAS-59122-7 under registration 524-581, and are referenced by MRID in the data matrix. Data demonstrating the efficacy of the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34/35Ab1 proteins produced in MON 89034 × TC1507 × MON 88017 × DAS-59122-7 relative to utilization of an interspersed in-field refuge is presented in Volume 2 of this submission.



Pages 615 - 624 *Confidential Statement of Formula may be entitled to confidential treatment*



Page 626

Confidential Statement of Formula may be entitled to confidential treatment

